Survival, primary stability and bone remodeling assessment of cementless sockets.

An appraisal of Wolff's Law in the acetabulum.

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Overleving, primaire stabiliteit en beoordeling van bot remodelering rondom ongecementeerde cups.

Een beoordeling van de wet van Wolff in het acetabulum.

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Doctoral Thesis

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Dit proefschrift draag ik op aan mijn (schoon) familie, vrienden en natuurlijk de belangrijkste personen in mijn leven:

Myrthe Marit Érinn
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Fheadfadh a bheith agat I gconai ballai do na gaotha,
dion le haghaidh an bháisteach, tae in aice leis an tine,
gaire chun cheer tu, iad siud gra agat in aice leat,
agus d'fheadfadh go leir do chroi mhian.

Dean Fioon Michael Pakvis
23-10-1975

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N1
BELFAST

Chapter 1:

Introduction, background and aims of this thesis

General introduction:

Osteoarthritis of the hip is a clinical diagnosis in patients who complain of pain and functional impairments during activity of daily life. The clinical diagnosis is confirmed by radiological evaluation, which is assessed using standard pelvic X rays and can be scored using the Kellgren-Lawrence classification. [1] When conservative treatment fails, a total hip arthroplasty (THA) will relieve pain, restores function of the hip joint and improve quality of life for patients with symptomatic hip osteoarthritis. In an article by Learmonth et al. in 2007, the authors considered the THA as the operation of the century. [2]
According to the Dutch Joint Registery (Landelijke Registratie Orthopedische Implantaten LROI) 25.642 implantations of primary hip arthroplasties were registered in the Netherlands in the year 2013. [3] This number is expected to grow during the following decades due to the aging of our population and the increasing demands of quality of life in younger patients with osteoarthritis. In the ninth annual report of the British National Health Service (NHS) on joint arthroplasty, it is reported that revisions of hip arthroplasties are increasing. [4] In 75% of the performed revisions (N= 6500) in the United Kingdom, the acetabular component was revised. It is therefore clear that the consistent quality of acetabular bone is of essential importance for the long-term fixation of primary and revision components.

The original idea of implant prosthetics as a surgical solution is attributed to the 16th-century French surgeon Ambroise Paré. The main surgical treatment of hip related morbidity was until the end of the 19 the century, based on resection arthroplasty. In 1840 an American surgeon (John Murray Carnochan) proposed the concept of placing a wooden construct between the ends of a joint. [5] Later, several surgeons developed soft tissue interposition strategies or localized cheilotomy to treat osteoarthritis of the hip. [6-10]
From the end of the 19th and the beginning of the 20th century surgeons designed hip arthroplasties made of different materials. The first recorded hip arthroplasty was made from ivory by prof T Gluck in 1890. [11] Delbet (1919) fabricated a new femoral head made of rubber. The first total hip arthroplasty has been attributed to Ernest Hey Groves in 1923. [12] From the development using glas by Smith-Peterson in 1925 [13] to vittalium [14] onto acrylic by the Judet brothers [15] and finaly towards metal, [16-19] surgeons slowly paved the way for the basis of the THA systems, as we know it today.

The first cementless reconstruction was designed by Wiles in 1938 using precisely fitted stainless steel components, which were fixated to the bone with screws and bolts. [16]
Further cementless developments were made by Ring in 1966 [18], Mittelmeier [20] and by an English surgeon called Lord in 1975. [21] Due to the good results obtained by Sir J. Charnley with cemented arthroplasties [19, 22], the development of cementless implants were over powered until literature pointed towards the so-called cement disease as a possible failure mechanism.
Many assumed that the deterioration and the reaction of the immune system towards the remaining parts of the cement mantle led to the formation of holes in the acetabulum surrounding the implant, resulting in loosening of the component and failure of the arthroplasty. This sparked the further development of cementless implants to avoid cement disease during the 1970's.
We now know that the term 'cement disease' was incorrect and that the radiographic changes seen on pelvic X-rays were due to osteolysis caused by wear particles generated at the articulation.

Despite the fact that numerous different acetabular components have been developed, each with different types of fixation and articulation, the acetabular component has remained, especially in cemented arthroplasties, the weakest link in total hip arthroplasty. [23] In several countries and especially as shown in reports from the Scandanavian hip arthroplasty registers, cement remains the preferred fixation method. [24,25]

The potential superiority of a cementless implant lies in the fact that a physical interaction is formed between a porous implant surface in which the surrounding bone can grow and form a living connection (bone ingrowth) between the implant and its host. The bone ingrowth leads to a long-term biological fixation that results in a long-term survival of the bone implant fixation. Unfortunately the bone implant interface is not the only factor that may lead to failure of a total hip arthroplasty.

The failure of cementless acetabular components is multifactorial; there are several mechanisms that could lead to failure and the requirement of a subsequent revision of the acetabular component. Fractures, malpositioning, polyethylene wear, instability, septic and aseptic loosening are all factors that affect the failure processes of THA components.
Acetabular fractures in primary THA surgery are more frequent in cementless compared to cemented hip arthroplasty. [26] In a historical cohort review of nearly 7200 arthroplasties the fracture rate was 0.4 %. [26] In 20% of the fracture cases a revision was needed, especially for monoblock elliptical sockets the fracture rate was high.
Malpositioning of the acetabular component could lead to revision due to recurrent dislocation and increased wear. [27,28] In 1978, Lewinnek recommended a 'safe-zone' of 40 ± 10 degrees of abduction and 15 ± 10 degrees of anteversion. [29] He found that the dislocation rate increased from 1.5% to 6.1% if these values were exceeded.
The increased polyethylene wear rate seen in cementless components is multifactorial. Besides malpositioning [28], other variables include; conformity of the articulating surface, polyethylene thickness, femoral head diameter, polyethylene locking mechanism, polyethylene additives [30], sterilization technique [31], manufacturing method [32], and the surgical implantation technique. [33]
Primary fixation is required to achieve bone ingrowth and osseointegration. When this fails, the socket will migrate and revision will be necessary. Primary fixation of the socket into acetabular bone in cementless hip arthroplasty is achieved using several different methods. Underreaming the acetabulum before implanting a socket press fit with or without additional fixation methods have been described by many authors with good clinical results. [34-38]

A surgical site infection is a complication with which every surgeon is familiar. Based on the work by Loius Pasteur, Jospeh Lister and Alexander Flemming, surgeons perform operations in sterile environments and use prophylactic antibiotics to prevent surgical site infections. However, acute periprosthetic infections unfortunately do occur but a revision is seldomely needed when treated with thorough and radical debridement and irrigation with retention of the prosthesis, followed by a period of antibiotic treatment. Successfull eridication of the infection can be up to 71 %. [39] If unsuccesfull, a single stage or two-stage revsion of the hip arthroplasty is warrented. According to the National Joint Registry of the UK, revision for infection has increased up to 12 % of the total revisions performed on an annual basis. [4]
Despite the importance of infection reduction, it is important to realize that aseptic loosening is the main reason for revision of a hip arthroplasty according to the National Joint Registry. [4]

In recentely published UK registry data, a cup revision was performed in 76 % of all hip revision surgeries during 2011/12, underlining the importance to work towards cups with a lower sensitivity to aseptic loosening. [4]
When focusing on asecptic loosening of cementless cups in particular, a number of issues play an important role. Firstly, adequate primary stability is required as it ensures the acetabular bone to grow into the microporous surface of the cementless socket, and form the fixation needed for a long-term survival. After the formation of this bone-prosthetic bonding, there are several factors that could interfere with the bone-prosthetic interface and lead to aseptic loosening and revision of the cup. Factors such as the increased joint/fluid pressure surrounding the artificial joint could jeopardize the interface formed between the bone and implant resulting in osteolysis leading to a revision. [40]
The acetabular bone quality and composition in which the cup is implanted is another major factor in the long-term survival of cementless sockets. There are several pathways that could lead to the deterioration of the bone quality and composition. Wear debris (PE or metal) in the encapsulated hip joint, leads to an uncontrolled inflammatory reaction that leads to bone loss (osteolysis) and consequent gradual failure of the bone-prosthetic connection. [41,42]

Considering the primary focus of this thesis, another potential mechanism that could lead to the deterioration of bone quality is based on Wolff's Law. [43] In the book “Das Gesetz der Transformation der Knochen” Julius Wolff laid the basis for his thoughts on the relationship between bone and its surrounding forces. Based on this theory, stress shielding is a well-known and described phenomenon in femoral bone after the implantation of a THA. Wolff's law is a theory developed by Julius Wolff (1836–1902 Figure 1) that states that bone will adapt to the loads under which it is placed. If loading on a particular bone increases, the bone will remodel itself over time to become stronger. However, when loading on bone decreases, the bone will reduce it's density due to the decreased turnover resulting in de decline of bone matrix and subsequent weakening.
Although some authors have studied acetabular stress shielding after implantation of a cup, many are sceptic about its clinical relevance. To our knowledge, the pro and contra arguments in literature on the clinical relevance of acetabular stress shielding are based on rigid cementless cups. [44-49] Because it is believed that stress-shielding increases with implant rigidity, it would be more appealing to implant a socket with an elastic modulus comparable to that of the surrounding acetabular bone. The load distribution within the bone will dispers in a more physiological patern and result in a milder adverse bone remodeling response according to Wolff's Law.

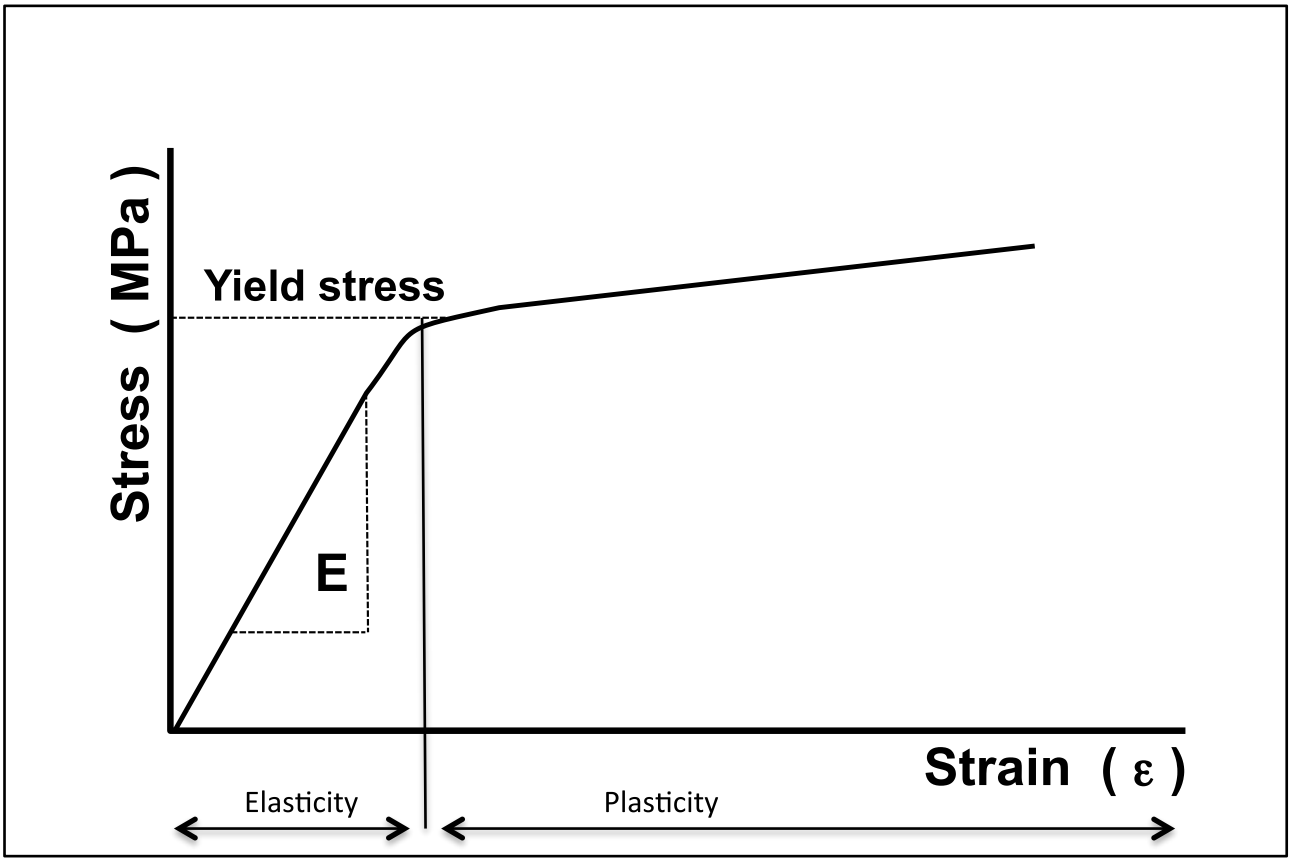
The following paragraphs will be used to explain the concept of elasticity in orthopedics.

Figure 1 Julius Wolff

What is elasticity?

All materials have elastic characteristics. Elasticity is very important because it enables the material to withstand forces without excessive deformation.
A material that behaves perfect elastistically will show a change in form (strain) via a constant (Young's modulus) due to a surrounding force (stress) and will return to its original shape and length when the surrounding force is removed (elasticity). The relationship between the stress and strain can be described in a stress-strain curve (Figure 2). When stresses become too high the material will deform and will be unable to restore to its initial shape or form (plasticity). The force (or rather stress) that is needed to induce plastic changes is called yield stress. All materials have their own Young's modulus. Materials with a low Young's modulus will require a low amount of stress to change in form. Rubber has a Young's modulus of 0.01 - 0.1 GPa compared to wrought iron, which has a Young's modulus of 190-210 GPa.

Figure 2 Stress-strain curve: E= Young (elastic) modulus.



The ratio for elasticity in orthopedics:

In orthopedics stress and its resultant deformation are very important. When walking, the contracting muscles (internal forces) and the external forces generated are transferred through the lower and upper leg bones, via the hip joint onto the acetabulum. Bones such as the femur are subjected to stress and strain during natural life. Its primary function is to resist deformation as a response to internal and external forces. [50] The knowledge how the femur reacts on bending forces when leaned on during stance or walking has been very important for fracture treatment with plates and intramedular nailing. The forces placed on bone can be divided in tensile, compressive and rotational forces, which account for the structure and distribution of cancellous and cortical bone.

When replacing a joint, the same stresses are transferred through the prosthesis onto the surrounding bone. When choosing a material as an articulating joint replacement the material requires biocompatibility, high yield and fatigue strength and a modulus of elasticity to interact with the surrounding bone and high wear resistance.

Bone is a living organism and consists mostly out of water, collagen and bone minerals (hydroxyapatite, silicon, carbonate, zinc etc). It contains two morphological subtypes of bone; cortical and cancellous (trabecular or spongeous) bone. Cancellous bone has a honeycomb structure and an elastic modulus that is lower than cortical bone but higher than the elastic modulus seen for cartilage.

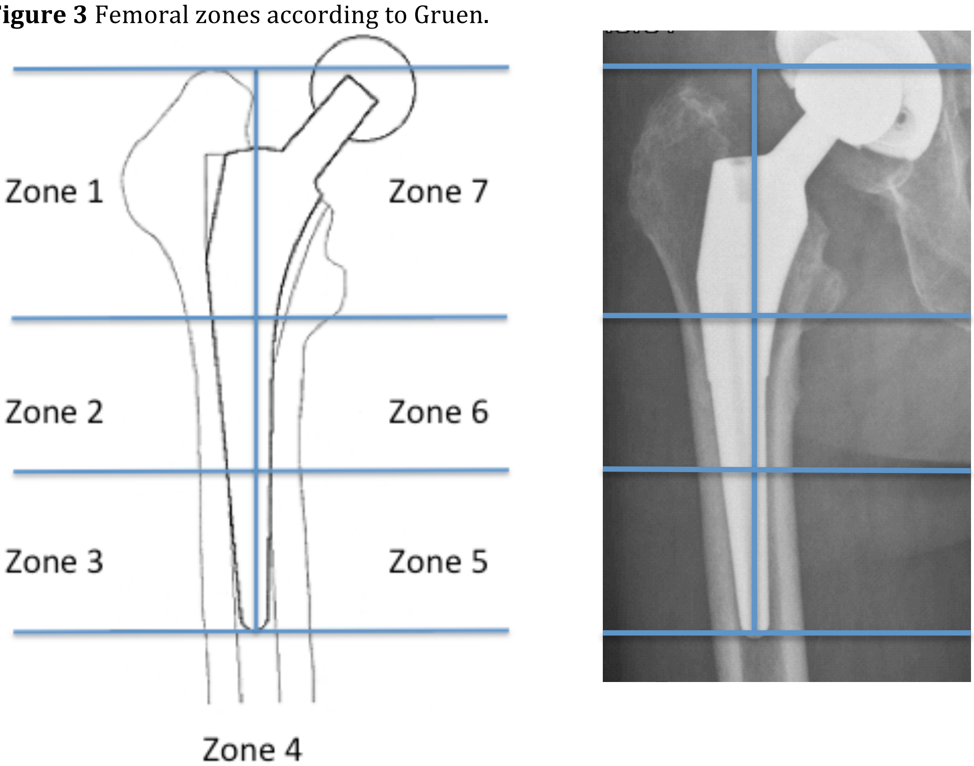
Bone has an active metabolism with a continuous cycle of bone formation and resorption (osteoblasts and osteoclasts) that is responsive to environmental changes such as the stress that is placed upon it.

According to Wolff's law bone, in a healthy person, will adapt to stress under which it is placed. [43] When the stress on bone is increasing, bone remodeling will ensure that the bone becomes stronger, when the stress on bone decreases bone will become weaker due to the diminished needs and changed bone turnover.

When stress on bone is diverted onto other regions due to constructs implanted in to the human body this is called stress shielding. Based on the principles as stated in Wolff's law the bone will remodel and become weaker in the areas where stress shielding takes place.

Stress shielding is not exclusive for a certain part of the human body. Femoral stress has been described after the implantation of hemi and total knee arthroplasties. [51-53] Remodeling of the femur after the replacement of the femoral head by a femoral component in a total hip arthroplasty has also been recognized in literature. [54-59] Femoral stress shielding is frequently seen in distally fixed femoral stems which reduce proximal loading of the femoral bone and cause bone resorption especially on the proximal medial femoral zone typically reported in Gruens zone 6 and 7. (Figure 3)

Figure 3 Femoral zones according to Gruen.



To our knowledge there has been only one clinical study examining the effect of a socket with low elastic modulus (Young's Modulus) on the development of the bone mineral density in the acetabulum. [60] The authors report the Dual-energy X-ray absorptiometry (DEXA) results at 2-years after implantation of a novel design acetabular construct. This construct has been formed according to the horseshoe shaped acetabular cartilage with a ligamentum capitis femoris recess.

As far as we are aware of, there has been no clinical study concerning the acetabular bone mineral changes using a low elastic modulus hemispherical cementless socket. Our hypothesis is that a more rigid component (increased Young's Modulus) is more deviating from the natural situation and therefore causes more peri-prosthetic bone resorption according to Wolff's law. In this thesis a socket is used made of a more flexible material that has the capability to deform after loading and transfers energy in a more physiological way onto its surrounding bone. Consequently, a more flexible cup (decreased Youngs Modulus) could prevent stress shielding and has been subject of study by Robert Mathys Sr. who developed the cementless RM elastic monoblock acetabular component in 1967 (Figure 4 and 5). This socket was based on the idea that the elastic modulus of the polyethylene RM socket (approx 1 GPA), in contrast to rigid metal shells (approx 100-200 GPA), better approximates the elastic properties of acetabular bone (approx 10-18 GPA). The resulting physiological distribution of articular forces protects the acetabular bone and provides optimal conditions for ingrowth, and subsequent long-term component fixation according to Wolff's Law.

Figure 4 Original cementless RM elastic, titanium plasma spray coated monoblock acetabular component developed in 1967

Figure 5 Press Fit cementless RM elastic, titanium coated monoblock acetabular component**.**

Aims of this thesis:

This thesis is based on the hypothesis that a cup with a lower elastic modulus will result in a more physiological stress transfer across the acetabular bone that will diminish the effect of stress shielding and reduce the decline of acetabular BMD after the implantation of an acetabular component. Hence, the emphasis will be on the BMD changes after the implantation of cementless sockets. This hypothesis was based on the biomechanical theory know as Wolfs Law. [43]
The aims of this thesis can be formulated as follows:

- Chapter 2: To explore the superior method (either cemented or cementless) of socket fixation reported in literature.
- Chapter 3: To review the long-term results of a cementless elastic cup in young patients.
- Chapter 4: To study the influence of elastic properties of cups on acetabular stress shielding and ingrowth potential in a finite element study.
- Chapter 5: To evaluate the stability of a cementless press-fit cup with or without additional screw fixation.
- Chapter 6: To determine the in-vivo effect of a rigid socket on acetabular bone stock using DEXA bone mineral density measurements.
- Chapter 7: To investigate the ultimate hypothesis that led to this thesis; a cup with elastic properties and a Youngs modulus close to bone will reduce stress shielding and outperform a more rigid cup design.

Literature:

1. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Ann Rheum Dis. 1957;16:494–502.
2. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. Lancet. 2007;370:1508-19.
3. LROI-rapportage Zicht op kwaliteit & veiligheid. Jaarrapportage uit de Landelijke Registratie Orthopedische Implantaten 2013. http://www.lroi.nl/nl/organisatie/nieuws/nieuws/lroi-rapportage-2013-zicht-op-kwaliteit--veiligheid.
4. The Ninth annual report NJR. http://www.njrcentre.org.uk/NjrCentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf
5. Carnochan JM. Mobilizing a patient's ankylosed jaw by replacing a block of wood between the raw bony surfaces after resection. Arch Med 1860;2:284.
6. Helferich H. Über Operationene an der Kniescheibe. Arch F Klin Chir. 1894;48:864.
7. Murphy JB. Surgical Clinics of Jhon B Murphy. IV. Philadelphia: Sanders; 1915. Cheilotomy.
8. Murphy JB. Trans Amer Surg Ass. 1904;22:213.
9. Lexer E. Über Gelenktrasportation. Med Klin Berlin. 1908;4:817.
10. Jones R, Lovett RW. Orthopaedic. Baltimore. Wm Wood 1929.
11. Gomez PF, Morcuende JA. "Early attempts at hip arthroplasty-1700s to 1950s". Iowa Orthop J. 2005;25:25–9.
12. E Hey Groves. Arthroplasty. B J Surgery. 1923;11:234-50.
13. Smith-Petersen M. Evolution of mould arthroplasty of the hip joint. J Bone Joint Surg. 1948;30:59.
14. Moore, A.T., Bohlman, H.R. Metal Hip Joint. A case report. J Bone Joint Surg. 1943;15:688-692.
15. Judet J, Judet R The use of an artificial femoral head for arthroplasty of the hip joint. J Bone Joint Surg. 1950;32:166-73.
16. Wiles P. The Surgery of the osteo-arthritic hip. Br J Surg. 1957;45:488–497.
17. McKee GK, Watson-Farrar J. Replacement of arthritic hips by the McKee-Farrar prosthesis. J Bone Joint Surg. 1966;482:245–259.
18. Ring PA. Replacement of the hip joint. Ann R Coll Surg Engl. 1971;48:344–355.
19. Charnley J Arthroplasty of the hip. A new operation. Lancet. 1961 May 27;1:1129-32.
20. Mittelmeier H. Fixing endoprostheses without cement using the principle of"weightbearing ribbing". Z Orthop Ihre Grenzgeb. 1974;112:27-33.
21. Lord G, Marotte JH, Blanchard JP, Guillamon JL, Gory M. Biological fixation of total hip arthroplasty without cement. Initial evaluation of 200 madreporic prostheses. Rev Chir Orthop Reparatrice Appar Mot. 1978;64 Suppl 2:5-13.
22. Charnley J Total hip replacement by low friction arthroplasty. Clin Orthop Relat Res. 1970;72:7-21.
23. Wroblweski B, Siney P. Charnley low friction arthroplasty of the hip. Long-term results. Clin Orthop Relat Res. 1993;292:191-201.
24. Hailer NP, Garellick G, Kärrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register. Acta Orthop. 2010;81:34-41.
25. Mäkelä KT, Eskelinen A, Pulkkinen P, Paavolainen P, Remes V. Results of 3,668 primary total hip replacements for primary osteoarthritis in patients under the age of 55 years. Acta Orthop. 2011;82:521-9.
26. Haidukewych GJ, Jacofsky DJ, Hanssen AD, Lewallen DG. Intraoperative fractures of the acetabulum during primary total hip arthroplasty. J Bone Joint Surg. 2006;88:1952-6.

27. Daines BK, Dennis DA. The importance of acetabular component position in total hip arthroplasty. Orthop Clin North Am. 2012;43:e23-34.
28. Little NJ, Busch CA, Gallagher JA, Rorabeck CH, Bourne RB. Acetabular polyethylene wear and acetabular inclination and femoral offset. Clin Orthop Relat Res. 2009;467:2895-900.
29. Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg. 1978;60:217-20.
30. Kurtz SM, Dumbleton J, Siskey RS, Wang A, Manley M. Trace concentrations of vitamin E protect radiation crosslinked UHMWPE from oxidative degradation. J Biomed Mater Res A. 2009;90:549-63.
31. García-Rey E, García-Cimbrelo E. Polyethylene in total hip arthroplasty: half a century in the limelight. J Orthop Traumtol. 2010;11:67–72.
32. Meding JB, Keaton M, Davis KE. Acetabular UHMWPE survival and wear changes with different manufacturing techniques. Clin Orthop Rel Res. 2011;469:405–411.
33. Nakahara I, Nakamura N, Nishii T, Miki H, Sakai T, Sugano N. Minimum five-year follow-up wear measurement of longevity highly cross-linked polyethylene cup against cobalt-chromium or zirconia heads. J Arthroplasty. 2010;25:1182–1187.
34. Kim Y. Long-term results of the cementless porous-coated anatomic total hip prosthesis. J Bone Joint Surg. 2005;87:623-7.
35. Kim YG, Kim SY, Kim SJ, Park BC, Kim PT, Ihn JC. The use of cementless expansion acetabular component and an alumina-polyethylene bearing in total hip arthroplasty for osteonecrosis. J Bone Joint Surg. 2005;87:776-80.
36. Firestone D, Callaghan J, Liu S, Goetz D, Sullivan P, Vittetoe D, Johnston R. Total hip arthroplasty with a cemented, polished femoral stem, and a cementless acetabular component. A follow-up study at a minimum of ten years. J Bone Joint Surg. 2007;89:126-32.
37. Suckel A, Geiger F, Kinz L, Wulker N, Garbrecht M. Long term results for the uncemented Zweymuller/alloclassic hip endoprosthesis. A 15-year minimum follow-up of 320 hip operations. J Arthroplasty 2009:24;846-53.
38. Pakvis D, Biemond L, van Hellemondt G, Spruit M. A cementless elastic monoblock socket in young patients: a ten to 18-year clinical and radiological follow-up. Int Orthop. 2011;35:1445-51.
39. Crockarell JR, Hanssen AD, Osmon DR, Morrey BF. Treatment of infection with débridement and retention of the components following hip arthroplasty. J Bone Joint Surg. 1998;80:1306-13.
40. Fahlgren A, Bostrom MP, Yang X, Johansson L, Edlund U, Agholme F, Aspenberg P. Fluid pressure and flow as a cause of bone resorption. Acta Orthop. 2010;81:508-16.
41. Maloney WJ, Smith RL, Schmalzried TP, Chiba J, Huene D, Rubash H. Isolation and characterization of wear particles generated in patients who have had failure of a hip arthroplasty without cement. J Bone Joint Surg. 1995;77:1301-10.
42. Abu-Amer Y, Darwech I, Clohisy JC. Aseptic loosening of total joint replacements: mechanisms underlying osteolysis and potential therapies. Arthritis Res Ther. 2007;9 Suppl 1:S6.
43. Wolff J. "The Law of Bone Remodeling". Berlin Heidelberg New York: Springer, 1986 (translation of the German 1892 edition)
44. Kress AM, Schmidt R, Vogel T, Nowak TE, Forst R, Mueller LA. Quantitative computed tomography-assisted osteodensitometry of the pelvis after press-fit cup fixation: a prospective ten-year follow-up. J Bone Joint Surg. 2011;93:1152-7.
45. Meneghini R, Ford K, McCollough C, Hanssen A, Lewallen D, Bone remodeling around porous metal cementless acetabular components. J Arthroplasty. 2010;25:741-7.

46. Mueller LA, Schmidt R, Ehrmann C, Nowak TE, Kress A, Forst R, Pfander D. Modes of periacetabular load transfer to cortical and cancellous bone after cemented versus uncemented total hip arthroplasty: a prospective study using computed tomography-assisted osteodensitometry. J Orthop Res. 2009;27:176-82.
47. Pitto RP, Bhargava A, Pandit S, Munro JT. Retroacetabular stress-shielding in THA. Clin Orthop Relat Res. 2008;466:353-8.
48. Wright J M, Pellicci P M, Salvati E A, Ghelman B, Roberts M M, Koh J L. Bone density adjacent to press-fit acetabular components. A prospective analysis with quantitative computed tomography. J Bone Joint Surg. 2001;83:529-36.
49. Wilkinson JM, Peel NF, Elson RA, Stockley I, Eastell R. Measuring bone mineral density of the pelvis and proximal femur after total hip arthroplasty. J Bone Joint Surg. 2001;83:283-8.
50. Currey JD. 2002. Bones: structure and mechanics. Princeton: Princeton University Press.
51. Järvenpää J, Soininvaara T, Kettunen J, Miettinen H, Kröger H. Changes in bone mineral density of the distal femur after total knee arthroplasty: a 7-year DEXA follow-up comparing results between obese and nonobese patients. Knee. 2014;21:232-5.
52. Soininvaara TA, Harju KA, Miettinen HJ, Kröger HP. Periprosthetic bone mineral density changes after unicondylar knee arthroplasty. Knee. 2013;20:120-7.
53. Lombardi A, Berend K, Adams J. Management of bone loss in revision TKA: it's a changing world. Orthopedics. 2010;7;33:662.
54. Bugbee WD, Culpepper WJ, Engh CA jr, Eng CA Sr. Long-term clinical consequences of stress-shielding after total hip arthroplasty without cement. J Bone Joint Surg. 1997;79:1007-12.
55. Engh CA, Bobyn JD, Glassman AH. Porous-coated hip replacement. The factors governing bone ingrowth, stress shielding, and clinical results. J Bone Joint Surg. 1987;69:45-55.
56. Huiskes R, Weinans H, van Rietbergen B, The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials. Clin Orthop Rel Res. 1992;274:124-134.
57. Nishino T, Mishima H, Kawamura H, Shimizu Y, Miyakawa S, Ochiai N. Follow-up results of 10-12 years after total hip arthroplasty using cementless tapered stem -- frequency of severe stress shielding with synergy stem in Japanese patients. J Arthroplasty. 2013;28:1736-40.
58. Ellenrieder M, Steinhauser E, Bader R, Mittelmeier W. How stiffness and distal interlocking of revision hip stems influence the femoral cortical strain pattern. J Orthop Sci. 2012;17:205-12.
59. Chandran P, Azzabi A, Andrews M, Bradley J. Periprosthetic bone remodeling after 12 years differs in cemented and uncemented hip arthroplasties. Clin Orthop Rel Res. 2012;470:1431-5.
60. Field RE, Cronin MD, Singh PJ, Burtenshaw C, Rushton N. Bone remodeling around the Cambridge cup: a DEXA study of 50 hips over 2 years Acta Orthop. 2006;77:726-32.

Chapter 2:

Is there evidence for a superior method of socket fixation in hip arthroplasty? A systematic review.

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Abstract:

Purpose:
Total hip arthroplasty has been a very succesful orthopaedic procedure. The optimal fixation method of the acetabular component however, has not yet been defined.
Methods:
We performed a systematic review using the Medline and Embase databases to find evidence for the superiority of cemented or cementless acetabular components on short- and long-term clinical and radiological parameters. Methodological quality for randomised trials was assessed using the van Tulder checklist, and for the non-randomised studies we used the Newcastle-Ottawa quality assessment scale.
Results:
Our search strategy revealed 16 randomised controlled trials (RCT) and 19 non-RCT studies in which cemented and cementless acetabular components are compared. A best evidence analysis for complications, wear, osteolysis, migration and clinical scores showed no superiority for either cemented or cementless socket in the RCTs. A best evidence analysis for non RCT studies revealed better osteolysis, migration properties and aseptic loosening survival for cementless sockets; however, wear and overall survival favoured the cemented sockets.
Conclusions:
We recommend that an orthopaedic surgeon should choose an established cemented or cementless socket for hip replacement based on patient characteristics, knowledge, experience and preference.

Introduction:

Total hip arthroplasty (THA) is a very successful orthopaedic procedure [1], but we still face the challenge of defining optimal socket fixation. The acetabular component is crucial for a good long-term outcome of THA. [2, 3] Long-term survival data on cemented hip arthroplasty has frequently been used to favour cement fixation. [4–6] In spite of these good long-term results, specific survival analysis of cemented hip arthroplasty showed increasing revision rates for acetabular compo- nents. [7, 8] In the early 1970s scientists developed cementless arthroplasties to solve the so-called cement disease, now known to be as a result of wear debris particles. Cementless fixation continued to develop and showed promising early to mid-term results. Long-term survival data and the further development of cementless fixation was needed to provide the right for existence for cementless sockets compared to long-term cemented data. [4, 9] The improvement of cementless sockets into third generation versions has been described in literature. [10, 11]
The choice whether to use cement or cementless fixation is based on knowledge, experience and personal preference. The reasons for choosing cementless fixation in high demand patients could be, for example, the absence of the cement–bone interface, biological fixation over time will profit from stresses imposed on the bone–implant interface, and prevents wear particles reaching peri-acetabular bone and resulting osteolysis.
Literature is providing us with excellent reports on long- term data for both cemented and cementless sockets. [4, 6, 12, 13] The question therefore remains valid as to which acetabular component fixation can be considered superior; cemented or cementless. For this we performed a systematic literature review in which we evaluated studies that compared cemented and cementless sockets to find evidence for the superior method of acetabular fixation. Since most randomised controlled trials (RCT) deal with a short- to medium-term follow-up, we also included cohort studies in which cemented and cementless sockets were compared. For these non-RCT studies there had to be sufficient internal control for bias and adequate handling of lost to follow-up patients in order to evaluate long-term effects.

Methods:

Search strategy for identification of studies
We conducted a literature study to identify all relevant 27andomized controlled trials and comparative cohort studies in which cemented and cementless sockets were compared. According to the QUOROM guidelines [14], a search was conducted through the Medline and Embase electronic databases for studies published between 1980 and December 2009. Our search strategy used the key- words: acetabul* AND cement* AND cementless OR uncemented OR non-cemented. Only publications written in the English or German language were considered for review. In an attempt to identify all relevant trials, literature references of the retrieved articles were exam- ined for additional relevant publications.

Selection of studies

One reviewer conducted the literature search and selected relevant literature in which comparison between cemented and cementless acetabular components has been reported through a hierarchical approach using title, abstract and full manuscript. The inclusion criteria were: primary total hip arthroplasty comparing cemented and cementless acetabular components, indication for performing THA had to be primary or secondary osteoarthritis, minimal follow-up had to be 12 months and data presented had to be clinical (complications, Harris hip score and survival) and radiological outcome measurements (wear, migration and osteolysis). Double publications of the same patient populations were not accepted.
Assessment of methodological quality
Articles that met all the mentioned criteria were indepen- dently examined by two reviewers (DP, GH). For the 28 randomized controlled trials the quality level was assessed using the van Tulder checklist. [15] (Table 1) When no consensus could be reached between the two reviewers, a third independent observer (WJ) was consulted to cast the decisive vote.
We used the Newcastle-Ottawa quality assessment scale to assess the quality level in the non-randomised controlled trials (n-RCT) [16] (Table 2). This analysis was performed by one author (DP) in simultaneous co-operation with the other reviewer (GH).

Best evidence synthesis

Best-evidence syntheses focuses on the “best evidence” in a field, the studies highest in internal and external validity, using well specified and defended a priori inclusion criteria, and use effect size data as an adjunct to a full discussion of the literature being reviewed. Based on literature we therefore used the van Tulder checklist for the selected RCT studies and the Newcastle-Ottawa checklist for the selected non-RCT studies. Articles that scored above 50% on the van Tulder or above 67% on the Newcastle-Ottawa checklists were selected and deemed to yield the best evidence. For double publications using the same patient population, the article with the highest checklist score was included in the best evidence synthesis. Neither in the van Tulder nor in the Newcastle- Ottawa checklist were the items weighted against their relevance. Therefore articles with elaborate statistics and articles with well-defined scores on other criteria could rank in the same category of 50% or higher. Although formally included in this review, these articles provided information of different quality. We tried to regain the most valuable statistical and textual information from the articles found in our review. Nevertheless, one could argue that the quality of the different types of information is similar.

Data collection
Two reviewers extracted data using a pre-developed data extraction form. Items in this form were study type, population characteristics, complications, treatment charac- teristics and outcome parameters (survival and radiological analysis).

Results:

Our search revealed 5,837 eligible articles. Initially 5,732 articles were excluded based on screening for our inclusion criteria. On the basis of the title and abstract, 65 articles were excluded leaving 40 articles from which 16 RCTs and 19 non RCT articles and five arthroplasty registries reports were isolated (Fig. 1). In these 16 publications cemented and cementless acetabular components were compared [17– 32] in a randomised clinical trial. These articles were published based on six performed RCTs and 879 hip arthroplasties. The 19 non-RCT studies were based on 4,479 arthroplasties. [33–51]
Methodological quality
Among reviewers, there was disagreement on 15% of the items of the van Tulder checklist. All disagreements were resolved in consensus between the reviewers and the independent reviewer. We simultaneously reviewed the non-RCT studies using the Newcastle-Ottawa quality assessment scale, all scores were reached by consensus. The methodological scores are based on the published articles and its contents, and imply no judgement of the performed trial.

Best evidence synthesis

There were three RCT studies, which scored 'yes' on more than 50% of the van Tulder criteria [20, 26, 30]. In orthopaedic surgery, surgeon blinding is not feasible. Therefore when re-evaluating the results of the van Tulder questionnaire we could select seven articles that scored yes on more than 50% of the van Tulder items. [20, 21, 23, 26– 28, 30] Excluding double publications we selected three articles and analysed short-term survival, complication (luxations, infections), early migration and clinical scores. In Table 3 study characteristics are summarised of the selected RCT studies. Twelve non-randomised studies scored more then 67% on the Newcastle-Ottawa quality assessment scale. For the best evidence synthesis in non-RCT studies we evaluated these 12 articles for wear, osteolysis, migration, long-term survival and clinical scores. In Table 4 the study characteristics are summarised for the selected non-RCT studies.
Wear was analysed using RSA in two RCT studies [27, 30] and five non-RCT studies (Table 5). Onsten and associates found no differences between the cemented and cementless sockets. [27, 28] Digas et al. described higher 3D penetration wear rates for cemented acetabular components ($p < 0.001$) [30]. These findings could be explained by the different sterilisation techniques (cemented ETO vs. cementless gamma radiation) used in this study. From the five non-RCT studies [33–36, 39], two [33, 39] showed superior wear characteristics for the cemented socket. All other studies showed no difference for wear between cemented and uncemented fixation at a minimum of ten years follow-up.
In the study published by Digas et al. [30], the authors found that the cementless sockets showed less osteolysis and even a decrease in radiolucent lines surrounding the component. In the group of non-RCT studies seven articles described osteolysis. Four reports described a difference between cemented and uncemented sockets. Zicat et al., Hartofilakidis et al. and Clohisy et al. all reported superiority for the uncemented socket at a minimal follow-up of nine years. [34, 36, 37] Ring et al. described superiority of the cemented socket only three years after implantation. [46]

Migration of acetabular components in the RCT study group was analysed using RSA. [27, 30] (Table 5) The general conclusion of these studies was that the method of fixation did not influence migration and rotation of the cup. In the non-RCT study group eight studies analysed migration using standard pelvic radiographs. Four studies reported superior fixation of uncemented sockets [33, 34, 37, 50], three of which reported these results based on minimal follow-up data of nine years. [33, 34, 37] Kordelle and Starker reported superior stability of the cemented socket six years after implantation. [42]
The Harris hip score (HHS) was used in all selected RCTs. Table 5 shows articles that present scores with description of average and range of outcome. None of the reported studies showed difference in favour of cemented or cementless acetabular components. Only four non-RCT studies reported clinical scores using the HHS and none showed superior mid- to long-term results for both cemented and uncemented sockets. [34, 35, 39, 44]
All retrieved RCT studies reported on follow-up data well below the ten-year interval. Laupacis et al. found more revisions in the cemented group compared to the cement- less arthroplasties (13 vs. 6). [26] They reported nine (7%) acetabular revisions due to aseptic loosening compared to four (3%) revisions in the cementless group. Although not significant, these results showed a trend in favour of the cementless sockets. All other selected articles published short- to medium-term follow-up without any difference between cemented and cementless arthroplasties with regard to acetabular survival [27, 30]. Long-term follow- up (over ten years) was seen in five non-RCT studies. [33, 34, 36, 39, 44] Three authors reported no statistical difference, whilst two authors favoured the cemented socket. [36, 44] In Hartofilakidis et al., different cementless sockets were compared with a Charnley cemented socket.
The cementless sockets showed superior aseptic loosening but were revised more often due to expansive osteolysis compared with the Charnley socket. [36] A cementless polyethylene Endler socket was used and later discarded by Kruckhans and Dustmann. [44] The authors noticed large osteolytic defects behind these cementless sockets and opted for revision. Later during the study period the Endler socket was replaced with the Allopro socket. Since this change the authors saw no difference in survival between the cemented and cementless group.
Complications were described in two RCT articles. Laupacis et al. described complications based on the revisions performed (sepsis, fractures aseptic loosening) [26]. Luxations or successfully treated infections, in which the prosthesis was retained, were not described. Onsten et al. described one dislocation, which they excluded from further follow-up. [27] The description and distribution of complications in the non-RCT group are presented in Table 6. There were no apparent significant differences between the cemented and cementless groups.

Discussion:

The selected RCT articles are only based on early- to medium-term follow-up and many articles lack the scientific quality to satisfactorily answer our basic question. The best evidence synthesis for these randomised studies showed no statistical difference for osteolysis, migration and cup survival. To provide a total literature overview we also reviewed all relevant non-RCT articles. The cemented socket was superior for long-term revision and polyethylene wear. The cementless socket provided better osteolysis and long-term cup migration results. As survival is the main resultant from wear, osteolysis, migration and clinical scores, cemented socket scored marginally better in this extensive literature review.

Investigators use systematic reviews to summarise existing data, refine hypotheses, estimate sample sizes, and help define future research agendas. Without systematic reviews, researchers may miss promising leads or may embark on studies of questions that have been already answered. Orthopaedic surgeons need review articles and other integrative publications to help generate clinical policies that optimise outcomes using available resources. Clinicians reason about individual patients on the basis of analogy, experience, and theory as well as research evidence. Awareness of a treatment's effectiveness does not confer knowledge about how to use that treatment in caring for individual patients. Although the RCT is viewed by many as the paradigm for clinical research, debate is growing stronger. [52, 53] Research designs with sufficient control of bias turned out to be as good as RCTs, especially when it came to evaluating long-term results.

Modern statistical approaches and careful selection of the research population can provide reasonably strong evidence. In surgery, especially in clinical practice, it is almost impos- sible to compare treatments since the effect of treatments will reveal themselves after at least a seven- to ten-year follow-up. In the case of wear and osteolysis the effect of treatment can be effectively evaluated after several years follow-up. Considering the statements given above, using validated questionnaires, carefully selected cohort studies with sufficient control could be regarded as the design of choice to evaluate surgical treatments instead of choosing the RCT.

The development of highly cross linked PE and addition of vitamin E to reduce wear [54, 55], more stable connections between the metal shell and PE insert, and development of monoblock systems as well as other tribological developments are potential answers that are all explored to improve outcome. In the RCT articles we studied there was no known difference between the PE types used, although in Digas et al. different sterilisation procedures were used. [30] In only two non-RCT articles, the authors provided additional information concerning the polyethylene used. Both used a metal femoral head on air gamma irradiated PE articulation with varying head diameter (22–28 mm). [34, 36] In both studies, PE wear was comparable for the cemented and cementless sockets but the incidence of osteolysis was significantly lower in cementless sockets. Riska et al. published medium-term follow-up results of a ceramic on ceramic articulation. [47] They found no wear in either group during their follow-up period, but did not focus and report osteolysis. In total five non-RCT studies described wear [34–37, 40], with two favouring the cemented socket. [33, 39]

Complications are seen in both cemented and cementless sockets; early complications such as dislocation and infection are indifferent of the type of acetabular fixation. Dislocation rates mostly depend on surgical experience and patient characteristics (indication, compliance, gender, age, muscle balance). [56] A difference between infection rates between cemented and cementless THA was not observed in a recently published Swedish registry report. [57] In the RCT articles reviewed in our report, complications were not the focus of investigation and therefore provide no additional information. The non-RCT studies show no apparent difference between the cemented and cementless sockets for dislocation and post-operative infections.

Proponents of cemented acetabular components argue that literature provides excellent long-term data concerning their use and that only short- to mid-term results show good results for uncemented sockets. The Scandinavian register provides a wealth of information on the performance of different arthroplasty components. In reports from this register, the most widely used cemented hip are the Charnley prosthesis, the Lubinus II and Exeter prosthesis. In contrast to the uniformity in cemented arthroplasty, the cementless components are heterogeneous in form, types, volume and fixation methods. [2, 58] We have also seen this in the non-RCT studies found during our search, in which various components are used and compared. This could lead to a selection bias. Local tradition, expertise on fixation type, surgical approach and diagnosis also provide different demographics and long-term results between cemented and cementless arthroplasties.. [58] Recently, Hailer et al. published a Swedish register report in which a comparison of the most commonly used cemented and cementless sockets showed no difference in revision for any reason. [57]

Only a few meta-analysis are known to us in which literature on cemented and uncemented hip arthroplasty are compared [59–61]. None however have performed an RCT meta-analysis concerning the acetabular component. Yahiro et al. showed higher aseptic failure in cemented cups. [59] Morshed et al. concluded that cement was still the first choice for acetabular fixation. [60] The articles they included consisted of RCT and non-RCT studies. Their literature search however was incomplete and ended at 2005. Huo et al. used the meta-analysis performed by Morshed et al. and provided an overview of the long-term literature of cemented components. [61] They concluded “the results of cemented cups have been inferior to cementless fixation in most published reports”.

Several other authors, who have frequently been referred to and found through our search, compared both fixation methods of acetabular components. [33–36] Gaffey et al. concluded superior results for cementless fixation with a follow-up of over ten years. [33] A matched pair analysis led to the conclusions that the cementless acetabular component showed significantly less loosening compared to the cemented version at nine to 11 years follow-up. [34] Superior aseptic survival for cementless fixation was also described by Hartofilakidis et al. [36] In evaluation of both types of fixation in patients who received a bilateral hip arthroplasty, Hearn et al. found no difference in the early- term follow-up in radiological and clinical scores. [35]

Nordic registry studies published during the last few years showed, in concordance with our results, ambiguous results concerning superiority of cemented and cementless sockets. [2, 58, 62] The Danish registry especially favours the cementless socket in patients below the age of 50 years. [2]

Knowledge, familiarity and further developments on cementless arthroplasty have altered the results of these components. Morshed et al. showed a positive correlation between implant survival and publication date for articles referring to cementless acetabular components. [60] The long-term, ten to 20 year results seem to be limited by acetabular osteolysis, although our review showed a lower incidence of osteolysis in cementless sockets. [34, 36, 37]

We conducted a literature search with which we have tried to determine the results comparing cemented and uncemented sockets. Long-term survival, osteolysis, migra- tion, wear and clinical scores are important factors on which we can determine superiority. Complications are ill- described in the RCT articles and provided no conclusive answers. The RCTs provide only short- to medium-term follow-up and therefore cannot fully answer our primary question of fixation superiority. We also reviewed non-RCT studies; these provided various long-term comparisons with ambiguous results in determining the superior fixation method. Complications such as dislocation and infections were better described in the non RCT group without apparent difference.

As orthopaedic surgeons and researchers we have to accept that RCT studies are difficult to perform and are not synonymous with the truth in orthopaedic care for our patients. We feel that it is imperative to use the highest grade of research available to find the optimal treatment in our practice. This could mean that non-RCT (prospective clinical trials) with adequate follow-up and measurement could set the gold standard in orthopaedic care.

The future of hip arthroplasty includes developing articulating surfaces to diminish wear, osteolysis and further investigation of other causes of loosening such as retro-acetabular stress shielding. This literary review pro- vides us with the information that the orthopaedic surgeon should use his or her knowledge, experience and preference to choose an established cemented or cementless socket for each patient treated.

Literature:

1. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. Lancet. 2007;370:1508–1519.
2. Eskelinen A, Remes V, Helenius I, Pulikkinen P, Nevalainen J, Paavolainen P. Total hip arthroplasty for primary osteo- arthrosis in younger patients in the Finnish arthroplasty register. 4,661 primary replacements followed 0–22 years. Acta Orthop Scand. 2005;76:28–41.
3. Caton J, Prudhon JL. Over 25 years survival after Charnley's total hip arthroplasty. Int Orthop. 2011;35:185–8.
4. Callaghan JJ, Templeton JE, Liu SS, Pedersen DR, Goetz DD, Sullivan PM, Johnston RC. Results of Charnley total hip arthroplasty at a minimum of thirty years. A concise follow-up of a previous report. J Bone Joint Surg. 2004;86:690–695.
5. Franklin J, Robertsson O, Gestsson J, Lohmander LS, Ingvarsson T. Revision and complication rates in 654 Exeter total hip replacements, with a maximum follow-up of 20 years. BMC Musculoskelet Disord. 2003;25:4–6.
6. Wroblewski BM, Siney PD, Fleming PA. Charnley low- frictional torque arthroplasty: follow-up for 30 to 40 years. J Bone Joint Surg. 2009;91:447–50.
7. Callaghan JJ, Liu SS, Firestone DE, Yehyawi TM, Goetz DD, Sullivan J, Vittetoe DA, O'Rourke MR, Johnston RC. Total hip arthroplasty with cement and use of a collard matte-finish femoral component. Nineteen to twenty-year follow up. J Bone Joint Surg. 2009;90:299–306.
8. Madey SM, Callaghan JJ, Olejniczak JP, Goetz DD, Johnston RC. Charnley total hip arthroplasty with use of improved techniques of cementing. The results after a minimum of fifteen years of follow up. J Bone Joint Surg. 1997;79:53–64.
9. Buckwalter AE, Callaghan JJ, Liu SS, Pedersen DR, Goetz DD, Sullivan PM, Leinen JA, Johnston RC. Results of Charnley total hip arthroplasty with use of improved femoral cementing techniques. A concise follow-up, at a minimum of twenty-five years, of a previous report. J Bone Joint Surg. 2006;88:1481–5.
10. Ries MD. Review of the evolution of the cementless acetabular cup. Orthopedics 2008;31(12 suppl 2).
11. Powers CC, Ho H, Beykirch SE, Huynh C, Hopper RH Jr, Engh CA Jr, Engh CA. A comparison of a second- and a third- generation modular cup design. Is new improved? J Arthroplasty. 2010;25:514–521.
12. Ihle M, Mai S, Pfluger D, Siebert W. The results of the titanium-coated RM acetabular component at 20 years: a long- term follow-up of an uncemented primary total hip replacement. J Bone Joint Surg. 2008;90:1284–1290.
13. Della Valle CJ, Mesko NW, Quigley L, Rosenberg AG, Jacobs JJ, Galante JO. Primary total hip arthroplasty with a porous- coated acetabular component. A concise follow-up, at a minimum of twenty years, of previous reports. J Bone Joint Surg. 2009;91:1130–1135.
14. Moher D, Cook DJ, Easwood S, Olkin I, Rennie D, Stroup D. Improving the quality of reports of meta-analyses of randomized controlled trials: the QOUROM statement Quality of reporting of meta-analyses. Lancet. 1999;354:1896–1900.
15. Van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the Cochrane collaboration back review group. Spine. 2003;28:1290–1299.

16. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Tugwell P. The Newcastle-Ottewa Scale (NOS) for assessing the quality of non-randomised studies in meta-analyses. Proceedings of the 3rd symposium on systematic reviews: beyond the basics. Oxford Centre for Statistics in Medicine, Oxford, England 2000.
17. Olsson E, Goldie I, Wykman A. Total hip replacement. A comparison between cemented (Charnley) and non-cemented (HP Garches) fixation by clinical assessment and objective gait analysis. Scand J Rehabil Med. 1986;18:107–116.
18. Wykman A, Olsson E, Axdorph G, Goldie I. Total hip arthroplasty. A comparison between cemented and press-fit non- cemented fixation. J Arthroplasty. 1991;6:19–29.
19. Nayak KN, Mulliken B, Rorabeck CH, Bourne RB, Woolfrey MR. Prevalence of heterotopic ossification in cemented versus non-cemented total hip joint replacement in patients with osteo- arthrosis: a randomized clinical trial. Can J Surg. 1997;40:368–374.
20. Devane PA, Robinson EJ, Bourne RB, Rorabeck CH, Nayak NN, Horne JG. Measurement of polyethylene wear in acetabular components inserted with and without cement. A randomized trial. J Bone Joint Surg. 1997;79:682–689.
21. Nayak NK, Mulliken B, Rorabeck CH, Bourne RB, Robinson EJ. Osteolysis in cemented versus cementless acetabular components. J Arthroplasty. 1996;11:135–140.
22. Rorabeck CH, Bourne RB, Mulliken BD, Nayak N, Laupacis A, Tugwell P, Feeney D. The Nicolas Andry award: comparative results of cemented and cementless total hip arthroplasty. Clin Orthop Relat Res. 1996;325:330–344.
23. Mulliken BD, Nayak N, Bourne RB, Rorabeck CH, Bullas R. Early radiographic results comparing cemented and cementless total hip arthroplasty. J Arthroplasty. 1996;11:24–33.
24. Rorabeck CH, Bourne RB, Laupacis A, Feeny D, Wong C, Tugwell P, Leslie K, Bullas R. A double-blind study of 250 cases comparing cemented with cementless total hip arthroplasty. Cost-effectiveness and its impact on health-related quality of life. Clin Orthop Relat Res. 1994;298:156–164.
25. Bourne RB, Rorabeck CH, Laupacis A, Feeny D, Wong C, Tugwell P, Leslie K, Bullas R. A randomized clinical trial comparing cemented to cementless total hip replacement in 250 osteoarthritic patients: the impact on health related quality of life and cost effectiveness. Iowa Orthop J. 1994;14:108–114.
26. Laupacis A, Bourne R, Rorabeck C, Feeny D, Tugwell P, Wong C. Comparison of total hip arthroplasty performed with and without cement: a randomized trial. J Bone Joint Surg. 2002;84:1823–1828.
27. Onsten I, Carlsson AS, Besjakov J. Wear in uncemented porous and cemented polyethylene sockets: a randomised, radio- stereometric study. J Bone Joint Surg. 1998;80:345–350.
28. Onsten I, Carlsson AS. Cemented versus uncemented socket in hip arthroplasty. A radiostereometric study of 60 randomized hips followed for 2 years. Acta Orthop Scand. 1994;65:517–521.
29. Onsten I, Carlsson AS, Ohlin A, Nilsson JA. Migration of acetabular components, inserted with and without cement, in one- stage bilateral hip arthroplasty. A controlled, randomized study using roentgenstereophotogrammetric analysis. J Bone Joint Surg. 1994;76:185–194.
30. Digas G, Thanner J, Anderberg C, Kärrholm J. Bioactive cement or ceramic/porous coating vs conventional cement to obtain early stability of the acetabular cup. Randomized study of 96 hips followed with radiostereometry. J Orthop Res. 2004;22:1035– 1043.

31. Digas G, Kärrholm J, Thanner J. Different loss of BMD using uncemented press-fit and whole polyethylene cups fixed with cement. Repeated DXA studies in 96 hips randomized to 3 types of fixation. Acta Orthop Scand. 2006;77:218–226.
32. McCombe P, Williams SA. A comparison of polyethylene wear rates between cemented and cementless cups. A prospective, randomised trial. J Bone Joint Surg. 2004;86:344–349.
33. Gaffey JL, Callaghan JJ, Pedersen DR, Goetz DD, Sullivan PM, Johnston RC. Cementless acetabular fixation at fifteen years. A comparison with the same surgeon's results following acetabular fixation with cement. J Bone Joint Surg. 2004;86:257– 261.
34. Clohisy JC, Harris WH. Matched pair analysis of cemented and cementless acetabular reconstruction in primary total hip arthroplasty. J Arthroplasty. 2001;16:697–705.
35. Hearn SL, Bicalho PS, Eng K, Booth RE Jr, Hozack WJ, Rothman RH. Comparison of cemented and cementless total hip arthroplasty in patients with bilateral hip arthroplasties. J Arthroplasty. 1995;10:603–608.
36. Hartofilakidis G, Georgiades G, Babis GC. A comparison of the outcome of cemented all-polyethylene and cementless metal-backed acetabular sockets in primary total hip arthroplasty. J Arthroplasty. 2009;24:217–225.
37. Zicat B, Engh CA, Gokcen E. Patterns of osteolysis around total hip components inserted with and without cement. J Bone Joint Surg. 1995;77:432–439.
38. Callaghan J, Pedersen D, Olejniczak J, Goetz D, Johnston R. Radiographic measurement of wear in 5 cohorts of patients observed for 5 to 22 years. Clin Orthop Relat Res. 1995;317:14–18.
39. Kim Y, Oh S, Kim J, Lee S. Total hip arthroplasty for the treatment of osseous ankylosed hips. Clin Orthop Relat Res. 2003;414:136–148.
40. Kirk P, Rorabeck C, Bourne R, Burkart B. Total hip arthroplasty in rheumatoid arthritis: comparison of cemented uncemented implants. Can J Surg. 1993;36:229–232.
41. Knessl J, Gschwend N, Scheier H, Munzinger U. Comparative study of cemented and cementless hip prostheses in the same patient. Arch Orthop Trauma Surg. 1989;108:276–278
42. Kordelle J, Starker M. Migration analysis of cemented muller polyethylene acetabular cups versus cement-free zweymul- ler screw-attached acetabular cups. Z Orthop Ihre Grenzgeb. 2000;138:46–51.
43. Krismer M, Fischer M, Klestil T, Frischhut B. Uncoated polyethelene RM acetabular component versus muller cemented acetabular component. A 4- to 8-year follow-up study. Arch Orthop Trauma Surg. 1991;110:195–199.
44. Kruckhans A, Dustmann H. Indications, methods, and results of cemented, hybrid, and cement-free implantations of THR. Surg Technol Int. 2004;12:253–257.
45. Pospula W, Abu Noor T, Roshdy T, Al MA. Cemented and cementless total hip replacement. Critical analysis and comparison of clinical and radiological results of 182 cases in Al Razi Hospital, Kuwait. Med Princ Pract. 2008;17:239–243.
46. Ring P. Uncemented acetabular replacement. Arch Orthop Trauma Surg. 1983;101:225–229.
47. Riska E. Ceramic endoprosthesis in total hip arthroplasty. Clin Orthop Relat Res. 1993;297:87–94.
48. Runkel M, Wenda K, Jaeger U, Rudig L, Roder W. 2- to 7- year results of cement-free and cemented joint replacement in femoral neck fractures and coxarthrosis. Aktuelle Traumatol. 1994;24:173–179.
49. Volkmann R, Schneider M, Bretschneider C, Weise K. More failures of uncemented acetabular screw-rings than of cemented polyethylene cups in total hip arthroplasties. Int Orthop. 1999;23:138–139.

50. Weber M, Berry D, Harmsen W. Total hip arthroplasty after operative treatment of an acetabular fracture. J Bone Joint Surg. 1998;80:1295–1305.
51. Wixson R, Stulberg S, Mehlhoff M. Total hip replacement with cemented, uncemented, and hybrid prostheses. A comparison of clinical and radiographic results at two to four years. J Bone Joint Surg. 1991;73:257–270.
52. Vandenbroucke JP. The HRT controversy: observational studies and RCTs fall in line. Lancet. 2009;373:1233–1235.
53. Rawlins MD. De Testimonio: on the evidence for decisions about the use of therapeutic interventions. The Harveian Oration 2008. The royal college of physicians. Clin Med. 2008;8:579–588.
54. Santavirta S, Bohler M, Harris WH, Konttinen YT, Muratogulu O, Rieker C, Salzer M. Alternative materials to improve total hip replacement tribology. Acta Orthop Scand. 2003;74:380–388.
55. Oral E, Muratoglu OK. Vitamin E diffused, highly crosslinked UHMWPE: a review. Int Orthop. 2011;35:215–223.
56. Mazoochian F, Pietschmann M, Hocke S, Fottner A, van Schulze- Pellengahr C, Jansson V. Hip dislocation following THA. Orthopade. 2007;36:935–943.
57. Hailer P, Garelilick G, Karrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish hip arthroplasty register. Acta Orthop Scand. 2010;81:34–41.
58. Havelin LI, Fenstad AM, Salomonsson R, Mehnert F, Furnes O, Overgaard O, Pedersen AB, Herberts P, Karrholm J, Garellick G. The Nordic arthroplasty register association. A unique collaboration between 3 national hip arthroplasty registries with 280,201 THRS. Acta Orthop Scand. 2009;80:394–401.
59. Yahiro MA, Gantenberg JB, Nelson R, Lu HT, Mishra NK. Comparison of the results of cemented, porous-in growth, and threaded acetabular cup fixation. A meta-analysis of the ortho- paedic literature. J Arthroplasty. 1995;10:339–350.
60. Morshed S, Bozic KJ, Ries MD, Malchau H, Colford JM Jr. Comparison of cemented and uncemented fixation in total hip replacement. Acta Orthop Scand. 2007;78:315–326.
61. Huo MH, Osier CJ. Is cement still a fixation option for total hip arthroplasty? J Arthroplasty. 2008;23:51–54.
62. Makela K, Eskellinen A, Pulkinnen P, Paavolainen P, Remes V. Total hip arthroplasty for primary osteoarthritis in patients fifty-five years of age or older. An analysis of the Finnish arthroplasty registry. J Bone Joint Surg. 2008;90:2160–2170.

Figure 1 Medline and Embase database, the QUOROM statement flow diagram.

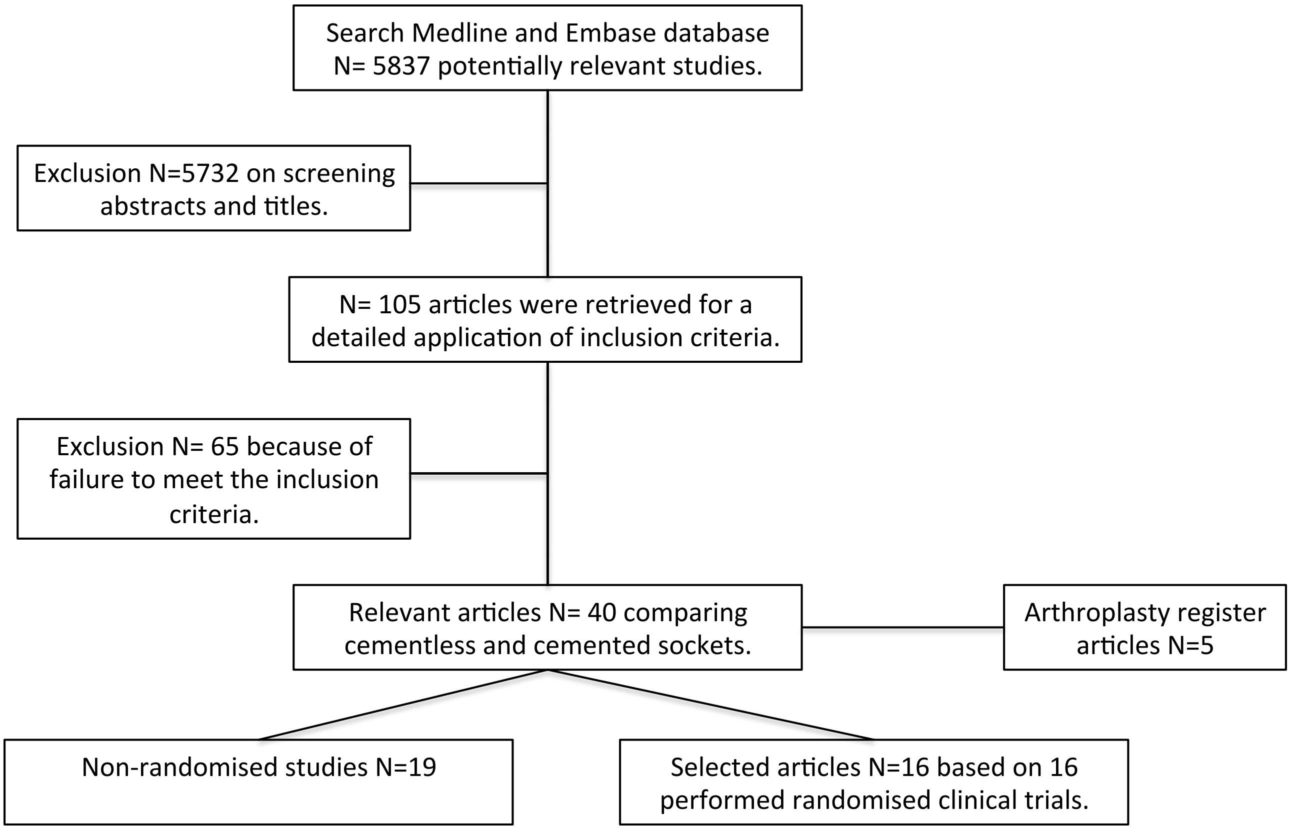

Table 1 Methodological criteria of the checklist of van Tulder et al.

Aspect	Description
Randomisation	Is a valid randomisation technique applied
Allocation concealment	Was the treatment allocation concealed
Prognostic factors	Are the patient groups comparable on prognostic factors
Patient blinding	Is the patient blinded for the treatment
Surgeon blinding	Is the surgeon blinded for the treatment
Outcome assessor blinding	Is the outcome assessor blinded for the treatment allocation
Co-interventions	Are the co-intervention described in sufficient detail
Compliance	Is the compliance acceptable
Drop-out	Is the drop-out rate given and acceptable
Timing	Is the timing of the outcome assessments comparable between groups and consistent within groups
Intention to treat	Is an intention to treat analysis given
Homogeneity	Is the patient group homogenous on prognostic factors

Table 2 Newcastle-Ottawa quality assessment scale cohort studies

Category	Description
Selection	1- Representativeness of the exposed cohort
	a) Truly representative of the average ____ (describe) in the community
	b) Somewhat representative of the average ____ in the community
	c) Selected group of users
	2-Selection of the non exposed cohort
	a) Drawn from the same community as the exposed cohort
	b) Drawn from a different source
	c) No description of the derivation of the non-exposed cohort
	3- Ascertainment of exposure
	a) Secure record
	b) Structured interview
	c) Written self report
	d) No description
	4- Demonstration that outcome of interest was not present at start of study
	a) Yes
	b) No
Comparability	5- Comparability of cohorts on the basis of the design or analysis
	a) Study controls____(selected the most important factor)
	b) Study controls for any additional factor
Outcome	6- Assessment of outcome
	a) Independent blind assessment
	b) Record linkage
	c) Self report
	d) No description
	7- Was follow-up long enough for outcomes to occur
	a) Yes
	b) No
	8- Adequacy of follow-up of cohorts
	a) Complete follow-up – all subjects encountered for
	b) Subject lost to follow-up unlikely to introduce bias – small number lost -> ____% (select an adequate %) follow-up, or description provided of those lost
	c) Follow-up rate <____% (select an adequate %) and no description of those lost
	d) No statement

Table 3 Characteristics of randomized controlled trials in the best evidence synthesis

Trial	Prothesis C:UC	Number of hips C:UC	Follow-up Mean (mo)	Age mean (Yr)	Clinical score	Radiological score	Complications
Onsten et al 1998	Charnley vs HG1	51:51	63	69	HHS	A+C	D
Laupacis et al 2002	Mallory Head	124:126	75	64	HHS	X	D
Digas et al 2004	Reflection vs Trilogy	59:37	24	67	HHS	A+B+C	X

C: UC cemented: uncemented, HHS Harris Hip Score, A wear, B osteolysis, C Migration, D Complications, X not reported.

Table 4 Characteristics of the non-randomised controlled trials included in the best evidence synthesis

Non RCT	Prosthesis	Hips (N)	FU mean (mo)	Age mean (Yr)	Clinical score	Radiological score
Clohisy et al 2001	Harris/HG	90	144	62	HHS	A+B+C
Gaffey et al 2004	Charnley/HG	261	180	67	X	A+B+C
Hartofilakidis et al 2009	Charnley/Multiple	117	168	43	X	A+B
Hearn et al 1995	Multiple/Multiple	72	48	61	HHS	B+C
Kim et al 2003	Multiple/Duraloc	95	120	47	HHS	A+B
Kordelle et al 2000	Muller/Zweymuller	47	72	62	X	C
Kruckhans et al 2004	X/Multiple	600	120	66	HHS	X
Pospula et al 2008	Exeter/Zweymuller	182	36	50	X	C
Ring et al 1983	X/Ring	1101	36	X	X	B+C
Riska 1993	Ceravit Osteal/ X	255	48 vs 84 [a]	62	X	A
Weber et al 1998	Multiple/Multiple	66	36 vs 120 [a]	52	X	C
Zicat et al 1995	AML/AML	137	108	56	X	B+C

RCT Rabdomised controlled trial, A Wear, B Osteolysis, C Migration, X not reported, HHS Harris Hip Score. [a] Separate follow-up duration for uncemented vs cemented sockets.

Table 5 Valid statistical analyses in the selected randomized controlled trial (RCT) and Non RCT studies containing Mean (Range)

Studies	Migration					
	Translation (mm)			Rotation (degrees)		
RCT						
Onsten et al 1998	Cemented		Uncemented	Cemented		Uncemented
Transversal	0.3 (0.01-2.5)		0.3 (0-1.5)	0.8 (0-8.7)		0.6 (0.1-3.0)
Longitudinal	0.4 (-0.2-5.0)		0.2 (-0.3-1.1)	0.7 (0-3.4)		0.7 (0-2.1)
Sagittal	0.2 (0-2.2)		0.3 (0-1.7)	0.6 (0.5.4)		0.6 (0-2.6)
Digas et al 2004	Cemented 1	Cemented 2	Uncemented	Cemented 1	Cemented 2	Uncemented
Transversal	-0.01 (-0.59-1.58)	-0.09 (-1.02-0.69)	0.12 (-0.33-3.22)	0 (-1.34-1.13)	-0.21 (-1.82-1.32)	0.23 (-0.60-6.54)
Longitudinal	0.12 (-0.05-0.71)	0.12 (-0.13-1.07)	0.15 (-0.13-1.00)	-0.05 (-2.45-2.20)	-0.08 (-1.49-0.75)	0.03 (-0.87-3.16)
Sagittal	-0.01 (-1.23-0.70)	0.02 (-0.72-0.49)	0.06 (-0.72-0.49)	-0.01 (-2.61-1.42)	0.06 (0.6-2.51)	0.09 (-0.49-1.42)
Non-RCT	Wear			Harris Hip Score		
	Cemented		Uncemented	Cemented		Uncemented
Clohisy et al 2001	0.08 (0-0.27)		0.08 (0-0.23)	87 (55-96)		92 (60-100)
Gaffey et al 2004	0.10 (0-0.25)		0.15 (0.01-0.36)	Not reported		Not reported
Hartofilakidis et al 2009	0.112 (0.01-0.34)		0.114 (0-0.5)	Not reported		Not reported
Kim et al 2003	0.24 (0.08-0.57)		0.32 (0.1-0.69)	82 (55-96)		82 (55-95)
Hearn et al 1995	Not sufficiently reported		Not sufficiently reported	92 (76-100)		91 (54-100)
RCT						
Onsten et al 1998	0.09 (0.02-0.26)		0.1 (0.03-0.22)	94 [a]		96
Digas et al 2004 [b]	0.45 (0.31-0.58)	0.42 (0.29-0.55)	0.21 (0.17-0.24)	95 (69-100)	89 (48-100)	94 (54-100)

[a] No statistical significant difference (CI 2.3-7.3)
[b] Wear measured as total 3D penetration

Table 6 Complications in the Non Randomised controlled trial (RCT) articles

Non RCT	Cemented			Uncemented		
	Dislocation (Revision)	Infection	Other Socket related	Dislocation (Revision)	Infection	Other Socket related
Clohisy et al 2001	1 (No)	0	0	4 (No)	0	Liner Number
Gaffey et al 2004	0	0	0	3 (Yes)	0	0
Hartofilakidis et al 2009	Nd	Nd	Nd	Nd	Nd	Nd
Hearn et al 1995	1 (Yes)	2	0	0	2	0
Kim et al 2003	2 (No)	2	0	2 (No)	2	0
Kordelle et al 2000	Nd	Nd	Nd	Nd	Nd	Nd
Kruckhans et al 2004	Nd	Nd	Nd	Nd	Nd	Nd
Pospula et al 2008	4 (No)	4	0	3 (No)	1	0
Ring et al 1983	Nd	Nd	Nd	Nd	Nd	Nd
Riska et al 1993	Nd	1	Cement number + Socket migration	Nd	2	Nd
Weber et al 1998 [a]	1 (yes)	0	0	0	0	0
Zicat et al 1995	0	0	0	2 (Yes)	0	0

Nd not described

[a] Unclear description concerning dislocation; one dislocationin the cemented socket resulting in revision and two dislocations without revision. The two dilocations were not subdivided in cementless or cemented.

Chapter 3:

A cementless elastic monoblock socket in young patients. A 10-18 year clinical and radiological follow up.

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Abstract:

Introduction:
The survival of acetabular components depends on several factors: wear, osteolysis and septic or aseptic loosening. Osteolysis seems to be the main cause for concern in cementless arthroplasties. Acetabular osteolysis results from particle debris and segmental unloading of acetabular bone by rigid sockets.
Methods:
We investigated a cementless, elastic monoblock socket with regard to acetabular osteolysis and aseptic loosening in a cohort of young patients. We evaluated 158 hip arthroplasties with a minimum follow up of 10 years (10-18) and a mean age of 42 years (18-50).
Results:
The overall survival rate at 14 years was 80% with a 98% survival rate for aseptic loosening. The mean polyethylene wear rate was 0.11 mm/y. Progressive acetabular osteolysis was seen in 3% of patients evaluated.
Conclusion:
We found low pelvic osteolysis rates, acceptable overall wear rates, satisfactory overall survival and excellent aseptic loosening survival rates for a cementless elastic monoblock socket in patients younger than 50 years. Ongoing tribology developments and knowledge concerning acetabular bone adaptations behind acetabular implants will further lower wear and osteolysis rates and optimize survival rates of cementless sockets.

Introduction:

Although cementless sockets seem to be the primary option for young patients, there are not many reports presenting long-term survival data for cementless sockets in patients less than 50 years. [1-5] Nearly all describe long-term results using rigid metal backed acetabular systems.
In 1967 Robert Mathys Sr. developed the uncoated cementless RM elastic monoblock acetabular component (Figure 1). This socket was based on the philosophy that the elastic modulus of the polyethylene RM socket (approx 1000 N/mm2), in contrast to rigid metal shells (approx 105,00 N/mm2), mimics the elastic properties of acetabular bone (approx 500-600 N/mm2). The resulting physiological distribution of articular forces protects the acetabular bone and provides optimal conditions for ingrowth, and subsequent long-term component fixation. The purpose of this retrospective study was to evaluate the effect of the cementless elastic monoblock socket on acetabular osteolysis and long-term survival for aseptic loosening in young patients.

Methods:

During the period from 1990 to 1997, 158 hip arthroplasties were performed on 131 patients less than 50 years old. The mean age was 42.4 (range 16 to 50) years; 67 were female and 64 were male. The indications for hip arthroplasty in this cohort are presented in Table 1.
A postero-lateral approach was used in all patients, with direct full weight bearing while allowing crutches during the first 6 weeks after surgery. The cementless monoblock RM (Mathys Ltd Betlach Switzerland) socket was used in all patients. This socket is an air gamma-radiated sterilised UHMWPE (Chirulen, ISO 5834/2 from GUR 1120 MediTECH, Vreden, Germany) polyethylene monoblock socket with a heat pressed titanium coating using two anchoring pegs and additional screw fixation for primary stability. In 99 hips a CLS Spotorno (Zimmer Ltd, Warsaw Indiana, US) femoral stem was used, 38 hips received an isoelastic RM (Mathys Ltd, Betlach, Switzerland) stem, 16 hips, a Wagner SL stem (Zimmer Ltd, Warsaw, Indiana, US), and in 5 hips a Wagner cone stem (Zimmer Ltd, Warsaw, Indiana US) was implanted. All femoral heads were 28 mm with Metal on PE articulation in 58 hips and Ceramic on PE in 100 hips. All patients received peri-operative antibiotics and deep vein thrombosis prophylaxis.
At the latest out patient visit, all patients were clinically evaluated using the Harris Hip score and the Merle D'Aubigne/Postel questionnaires (Figure 2). We defined an excellent to good clinical score as HHS of 100-80 and Merle D'Aubigne/Postel of 18-14.

Radiographic evaluation
Observations and measurements were based on standardized anteroposterior pelvic and lateral hip radiographs made early in the post-operative period and at the latest follow-up visit. Correction of magnification was attained for all measurements using the femoral head.
All radiographs were evaluated by two authors (DP, JB) and disagreements were resolved through consensus.
Socket migration was evaluated using the method described by Massin et al. [6] Acetabular component migration of > 3 mm in the vertical or horizontal plane and change of cup inclination of > 8 degrees were classified as radiographically loose. [7]

Wear was measured using methods described by Kang. [8] Acetabular osteolysis was evaluated using the acetabular zones described by De Lee and Charnley. [9] It was deemed significant when progressive, measuring > 2 mm and occupying more than 50% of the acetabular zones. Heterotopic ossification (HO) was graded according to Brooker et al. [10]

Statistical analysis

We classified failure as revision of the acetabular component due to septic or aseptic loosening and PE wear. Survival analysis was calculated using the Kaplan-Meier method. We performed both best and worst case scenario analysis during the survival analysis. A logistic regression model was performed to evaluate the effect of patient age, gender, stem type, diagnosis, previous surgery and acetabular inclination on acetabular revision. Cox's proportional hazards model was used to examine the survival rates for different patient and component factors.

Results:

The mean follow-up period was 13.2 (range 10 to 18) years. During this period, 4 patients (5 hips) died without any relationship to the performed arthroplasty. Clinical and radiographic analysis showed no complications of their arthroplasty. Four patients were lost to follow up, mainly due to emigration.

Acetabular survivorship analysis

During the study inclusion period 158 hips arthroplasties were performed in 131 patients. Acetabular revision had been performed on twenty patients by the latest follow up. During our latest follow up 2 patients were scheduled for acetabular revision. Our survival analysis was performed on the basis of 22 (14%) acetabular revisions. The reasons for revision and additional data are listed in Table 3.

At 10 years 4 patients (3%) had undergone acetabular revision. At the time of the latest follow up 2 patients (1%) had undergone revision for aseptic loosening, 2 patients (1%) for malposition and 4 patients (3%) for trauma sequelae. In 7 patients (4%) acetabular wear was the primary reason for revision. During 7 (4%) femoral revisions the surgeon perioperatively decided to revise the acetabular component for minor to severe wear of the socket.

A worst-case survival analysis at 10 years showed 98% (95% confidence interval, 95 to 100) survival and 80% (95% confidence interval, 72 to 89) at 14 years (Figure 3). Survival for aseptic loosening of the RM cup at 10 and 14 years is 99% (95% confidence interval, 98-100) and 98% (95% confidence interval, 96 to 100) (Figure 4). Survival analysis for wear shows 99% (95% confidence interval, 98 to 100) survival at 10 years and 86% (95% confidence interval, 78 to 94) at 14 years follow up.

Wear analysis for the two featured articulations shows 80% (95% confidence interval 68 to 91) survival for the metal on PE articulations and 95% (95% confidence interval 87 to 100) survival for the ceramic on PE articulations at 14 years (Figure 5).

Log rank analysis for type of articulation and revision shows statistical difference ($p=0.009$) in favor of the Ceramic on PE articulations. The Cox proportional hazard regression analysis showed a 6.8 (1.5 to 30.5) times higher odds ratio for revision in a metal on PE articulation. A logistic regression model showed no effect on revision for factors including age, stem type, gender, diagnosis, previous surgery and, acetabular inclination.

Femoral revision

During the follow up period, 24 patients (15%) underwent femoral revisions. Sixteen RM stems, 6 CLS stems and 2 Wagner stems had been revised previous to the follow up. During 7 of these procedures, acetabular revision was simultaneously performed due to wear of the monobloc RM system. All patients who underwent exclusively a femoral revision remained in the survival analysis for the RM acetabular component.

Clinical results

One hundred and two (79%) of the remaining 130 hip arthroplasties scored excellent to good on the HHS. Nine (7%) showed fair and 19 patients (15%) had poor results at the latest clinical evaluation. Only 11 (9%) patients showed poor clinical results using the Merle D'Aubigne/Postel questionnaire. All other patients scored excellent to good on the Merle D'Aubigne/Postel questionnaire.

Radiographic results

Pelvic radiographs were available for all patients who were not lost to follow up and who were still alive. In Table 2 radiographic parameters are shown comparing the revised group with the non-revised group. At the final follow up 3 sockets showed a significant advancement in inclination and also showed ~~a~~ significant horizontal and vertical migration. Two patients showed only a significant vertical migration.

Two patients were considered as outliers for horizontal and vertical migration (5.0 mm; 10.5 mm and 10.5 mm; 32.5 mm, respectively). The first patient showed excellent clinical scores with significant wear and refused revision due to lack of symptoms. The second patient had a poor clinical score, showed significant wear but refused revision. We analysed the migration patterns for the two articulations used in our study. All reported outliers mentioned above were patients with a ceramic on PE articulation. We found no statistical difference for either horizontal (mean: 1.5mm; 1.9mm), vertical (mean: 1.8mm; 2.3mm) and inclination (mean: 2.3°; 2.8°) migration for respectively the metal on PE and ceramic on PE articulations. Heterotopic ossification was seen in 46 patients (Grd 1=18, Grd 2=11, Grd 3=15, Grd 4=2). Progressive significant acetabular osteolysis was seen in 4 patients (3%), mainly cavitary osteolysis found in De Lee and Charnley zone 1 adjacent to the fixating screws.

Complications

In our cohort seven arthroplasties (4%) had one or more dislocations, 2 of which resulted in simultaneous acetabular and femoral revision and in 3 cases, isolated femoral stem revisions. There were 3 infections for which one patient underwent operative debridement. Femoral fractures were seen in 6 cases: 3 during implantation and 3 during the follow up period. One patient showed sciatic nerve irritation due to a postoperative haematoma, symptoms resolved following conservative treatment. Surgical treatment was indicated for 2 patients suffering from Grd 4 HO. Two patients had postoperative urinary tract infections, which were treated with oral antibiotics.

Discussion:

Total hip arthroplasty (THA) is a very successful orthopaedic procedure [11], but there is no consensus in defining the optimal socket fixation method, especially for young patients. [12] Although cementless sockets are often advocated in young patients, patients younger than 50 years are more susceptible to wear, osteolysis, implant loosening, and failure because of their increased activity level. [13-15] Publications specifically investigating long-term results for a homogenous group of cementless sockets in patients under 50 years are scarce. McLaughlin and Lee reported a 56% revision rate at 10 years using the T-Tap socket in patients aged 50 years or less. [1] Comparable results were published by Utting et al who reported 55% impending Harris Galante I revisions at a mean follow up of 13.6 years for patients with a mean age of 40 years. [4] The same socket was used by Crowther and Lachiewicz and Duffy et al, both with better survival rates of 98% respectively 88% at 10 years in young patients. [2,3] Kim et al implanted 102 Duraloc Option acetabular components in 73 patients with a mean age of 38 years. [5] They reported a cumulative acetabular survival of 99% at 11 years.
All these publications however, concern long term-results of modular acetabular systems.
In a review of the Finnish arthroplasty register in 2008, Makela et al raised concerns on wear related revisions for modular cementless sockets. [16] The authors emphasized this problem because of the high proportion of reported liner/wear related problems. In 2002 Young et al reported a comparative study between modular and monoblock systems, both using PE sterilized by gamma irradiation in air. [17] In that study the monoblock system demonstrated a lower mean true wear rate and significant (p=0.01) less osteolysis. Liner-shell conformity, optimalization of clearance, increased polyethylene thickness, absence of a locking mechanism and no liner-shell micro-motions (backside wear) are factors in favour of monoblock systems.

The air gamma irradiated PE we used in our study, showed a mean articular wear of 0.11 mm/yr. These values correspond well with articular wear in literature on cementless modular sockets (0.08 and 0.18) [18,19], monoblock sockets (0.05 to 0.17) [20,21] and even cemented sockets in young patients (0.06 and 0.12). [22,23] In our study, approximately 1/3 of the articulations used were metal on PE. In accordance with other authors [21,24,25], this resulted in an increased risk for revision for PE wear with a survival of 80% (95% confidence interval 68 to 91) at 14 years compared with a superior long term survival rate of 95% (95% confidence interval 86.8 to 100) for a ceramic on PE articulation. The ceramic on PE articulations showed a none significant higher mean migration rate mainly due to the several outliers found in our analysis.

Seven sockets were revised during femoral revision surgery. Regional acetabular PE wear was estimated to range from minor to severe during femoral revision surgery although during preoperative planning there was no intention to perform an acetabular revision. The decision to revise the acetabular component was simplified due to the relative ease with which the socket can be revised. Nearly all known monoblock sockets are manufactured by fixing a PE liner into a rigid metal shell during fabrication. In case of an impending revision, the all poly construct of the RM socket has the advantage over these metal-shelled monoblock sockets due to its relatively easy revision method. [26,27] Using an acetabular reamer and sufficient irrigation, the socket can be removed with the least amount of acetabular bone stock damage.

Almost all progressive peri-acetabular osteolysis seen on the pelvic radiographs were cavitary osteolytic lesions mainly found in De Lee and Charnley zone 1. This could be explained by the adjacent screw, which can act as a pathway for PE particles.
The osteolysis rates found in our study on the RM socket, compares favourably to data reported on cementless acetabular components [17,28] and are comparable to the known low osteolysis rates for monoblock sockets. [21,29]

The concept of a coated elastic monoblock socket has remained unique. The advantage of this concept is the osseointegration potential of the titanium coating, which does not affect the elastic properties of the socket. The elastic modulus of the socket permits transmission of physiological articular stresses and thereby reduces acetabular stress shielding and the development of acetabular osteolysis.
In 2008 Ihle et al reported the longest follow up for an RM socket. [24]. They presented data on 93 consecutive RM sockets at a mean follow up of 19 years. Cumulative acetabular survival analysis for any reason showed excellent survival of 83% (95% confidence interval 73 to 90) at 20 years. Regression analysis showed a 4-fold risk for acetabular revision in younger patients.
A worst-case survival analysis of the 158 reported hip arthroplasties in our study, showed the somewhat lower survival of 80% (95% confidence interval, 72 to 89) at 14 years. The patients presented in our study, however, had a lower mean age (42 vs. 52) and there were more metal on PE articulations that resulted in more wear and revisions.

This study presents long-term follow up data concerning a cementless elastic monoblock socket in a large cohort of young patients with a nearly complete clinical and radiological follow up. A drawback of this study is the retrospective design; two different articulation types and the different stem types used which both interfere with determining the survival of just the RM socket. Although this study has limitations, our report shows good clinical outcome, low osteolysis rates and excellent long-term aseptic loosening survival for a cementless elastic socket in young patients.
Ongoing tribology developments and knowledge concerning acetabular bone adaptations behind acetabular implants will further lower wear and osteolysis rates and could optimize survival rates of cementless sockets.

Literature:

1. McLaughlin JR, Lee KR. Total hip arthroplasty in young patients. 8- to 13 years results using an uncemented stem. Clin Orthop. 2000;373:153-63.
2. Crowther JD, Lachiewicz PF. Survival and polyethylene wear of porous coated acetabular components in patients less than fifty years old: results at nine to fourteen years. J Bone Joint Surg. 2002;84:729-735.
3. Duffy GP, Prpa B, Rowland CM, Berry DJ. Primary uncemented Harris-Galante acetabular components in patients 50 years old or younger. Results at 10 to 12 years. Clin Orthop. 2004;427:157-61.
4. Utting MR, Raghuvanshi M, Amirfeyz R, Blom AW, Learmonth ID, Bannister GC. The Harris-Galante porous-coated hemispherical, polyethylene-lined acetabular component in patients under 50 years of age. A 12 to 16-year review. J Bone Joint Surg. 2008;90:1422-7.
5. Kim Y-H, Choi Y, Kim JS. Cementless total hip arthroplasty with ceramic-on-ceramic bearing in patients younger than 45 years with femoral-head osteonecrosis. Int Orthop. 2010;34:1123-7
6. Massin P, Schmidt L, Engh CA. Evaluation of cementless acetabular component migration. An experimental study. J Arthroplasty. 1989;4:245-51.
7. Engh CA, Griffin WL, Marx C. Cementless acetabular components. J Bone Joint Surg. 1990;72:53-9.
8. Kang JS, Park SR, Ebramzadeh E, Dorr LD. Measurement of polyethylene wear in total hip arthroplasty-accuracy versus ease of use. Yonsei Med J. 2003;44:473–8.
9. DeLee JB, Charnley J. Radiographical demarcation of cemented sockets in total hip replacement. Clin Orthop. 1976;121:20-32.
10. Brooker AF, Boweman JW, Robinson RA, Riley LH jr. Ectopic ossification following total hip replacement: incidence and a method of classification. J Bone Joint Surg. 1973;55:1629-32.
11. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. Lancet. 2007;370:1508-1519.
12. Eskelinen A, Remes V, Helenius I, Pulikkinen P, Nevalainen J, Paavolainen P. Total hip arthroplasty for primary osteoarthrosis in younger patients in the Finnish arthroplasty register. 4.661 primary replacements followed 0 – 22 years. Acta Orthop Scand. 2005;76:28-41.
13. Furnes O, Lie SA, Espehaug B, Vollset SE, Engesaeter LB, Havelin LI. Hip disease and the prognosis of total hip replacements. A review of 53,698 primary total hip replacements reported to the Norwegian Arthroplasty Register 1987-99. J Bone Joint Surg. 2001;83:579-86.
14. Kim YH, Oh SH, Kim JS. Primary total hip arthroplasty with a second-generation cementless total hip prosthesis in patients younger than fifty years of age. J Bone Joint Surg. 2003;85:109-14.
15. Kearns SR, Jamal B Rorabeck CH, Bourne RB. Factors affecting survival of uncemented total hip arthroplasty in patients 50 years or younger. Clin Orthop. 2006;453:103-9.
16. Makela KT, Eskelinen A, Pulikkinen P, Paavolainen P, Remes V. Total hip arthroplasty for primary osteoarthritis in patients fifty-five years of age or older. An analysis of the Finnish arthroplasty registry. J Bone Joint Surg. 2008;90:2160-70.
17. Young AM, Sychterz CJ, Hopper RH Jr, Engh CA et al. Effect of acetabular modularity on polyethylene wear and osteolysis in total hip arthroplasty. J Bone Joint Surg. 2002;84:58-63.
18. Ito H, Matsuno T, Aok Y, Minami A. Total hip arthroplasty using an Omniflex modular system: 5 to 12 years follow up. Clin Orthop. 2004;419:98-106.

19. Krieg A.H, Speth B.M, Ochsner P.E. Backside volumetric change in the polyethylene of uncemented acetabular components. J Bone Joint Surg. 2009;91:1037-43.
20. Hinrichs F, Boudriot U, Held T, Griss P (2001). 10 years results with a Monobloc hip endoprosthesis cup with multilayer titanium mesh coating for cement-free implantation. Z Orthop Ihre Grenzgeb. 2001;139:212-6.
21. Berli BJ, Ping G, Dick W, Morscher EW. Nonmodular flexible press-fit cup in primary total hip arthroplasty. 15-year follow up. Clin Orthop. 2007;461:114-121.
22. Wroblewski BM, Siney PD, Fleming PA. Charnley low-frictional torque arthroplasty: follow-up for 30 to 40 years. J Bone Joint Surg. 2009;91:447-50.
23. Ballard WT, Callaghan JJ, Sullivan PM, Johnston RC. The results of improved cementing techniques for total hip arthroplasty in patients less than fifty years old. A ten-year follow-up study. J Bone Joint Surg. 1994;76:959-64.
24. Ihle M, Mai S, Pfluger D, Siebert W. The results of the titanium-coated RM acetabular component at 20 years: a long-term follow-up of an uncemented primary total hip replacement. J Bone Joint Surg. 2008;90:1284-90.
25. D'Antonio JA, Sutton K. Ceramic materials as bearing surfaces for total hip arthroplasty. J Am Acad Orthop Surg. 2009;17:63-8.
26. Mallory TH, Lombardi AV Jr, Fada RA et al. Non-cemented acetabular component removal in the presence of osteolysis. Clin Orthop. 2000;381:120-8.
27. Horne G, Devane PA, Dalton DJ. Does pelvic osteolysis occur with a Nonmudular Uncemented Acetabular Component? J Arthroplasty. 2006;21:185-90.
28. Della Valle CJ, Mesko NW, Quigley L, Rosenberg AG, Jacobs JJ, Galante JO. Primary total hip arthroplasty with a porous-coated acetabular component. A concise follow-up, at a minimum of twenty years, of previous reports. J Bone Joint Surg. 2009;91:1130-5.
29. Macheras G, Kateros K, Kostakos A, Koutsostathis S, Danomaras D, Papagelopoulos PJ. Eight- to ten-year clinical and radiographic outcome of a porous tantalum monoblock acetabular component. J Arthroplasty. 2009;24:705-9.

Figure 1: A photograph of the cementless elastic monoblock Robert Mathys socket.

Figure 2: Study inclusions

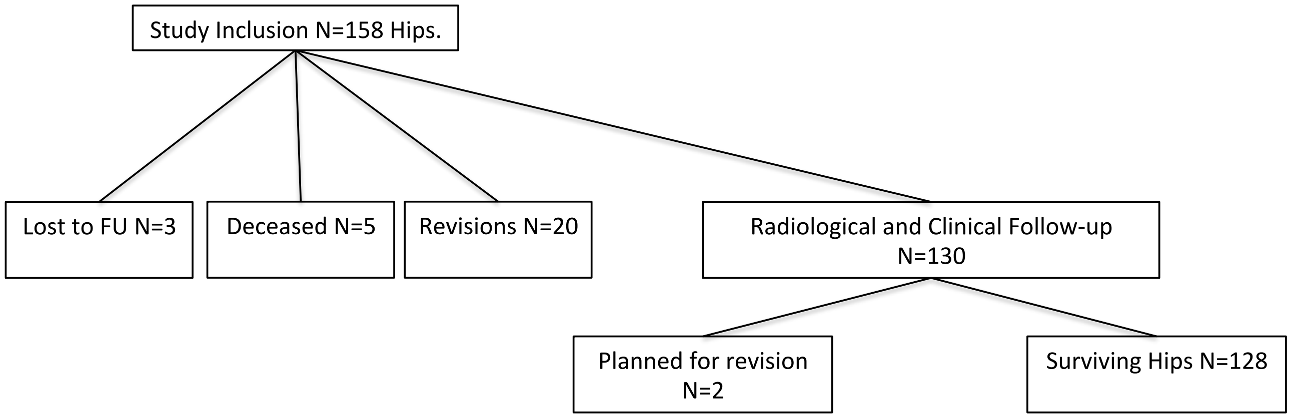

Figure 3: Kaplan-Meier curve of the overall survival of the RM cup.

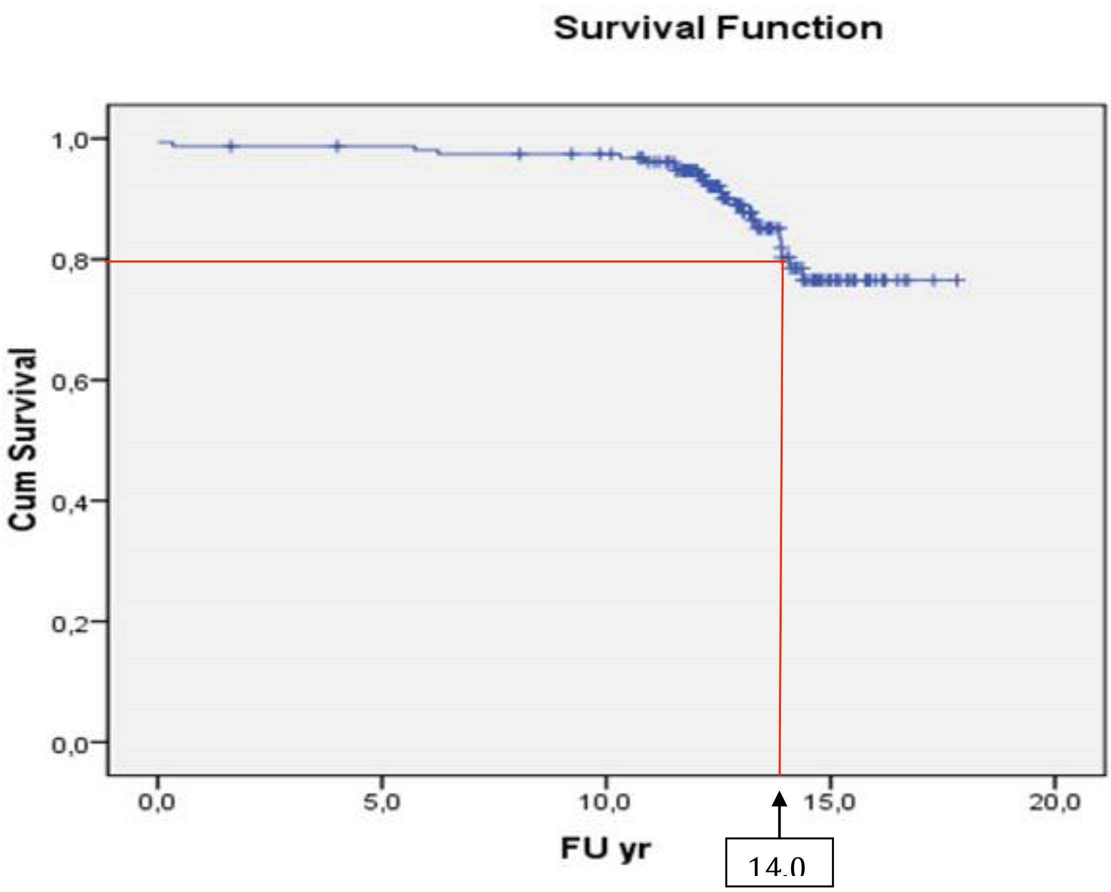

Figure 4: Kaplan-Meier curve of the aseptic loosening survival of the RM cup.

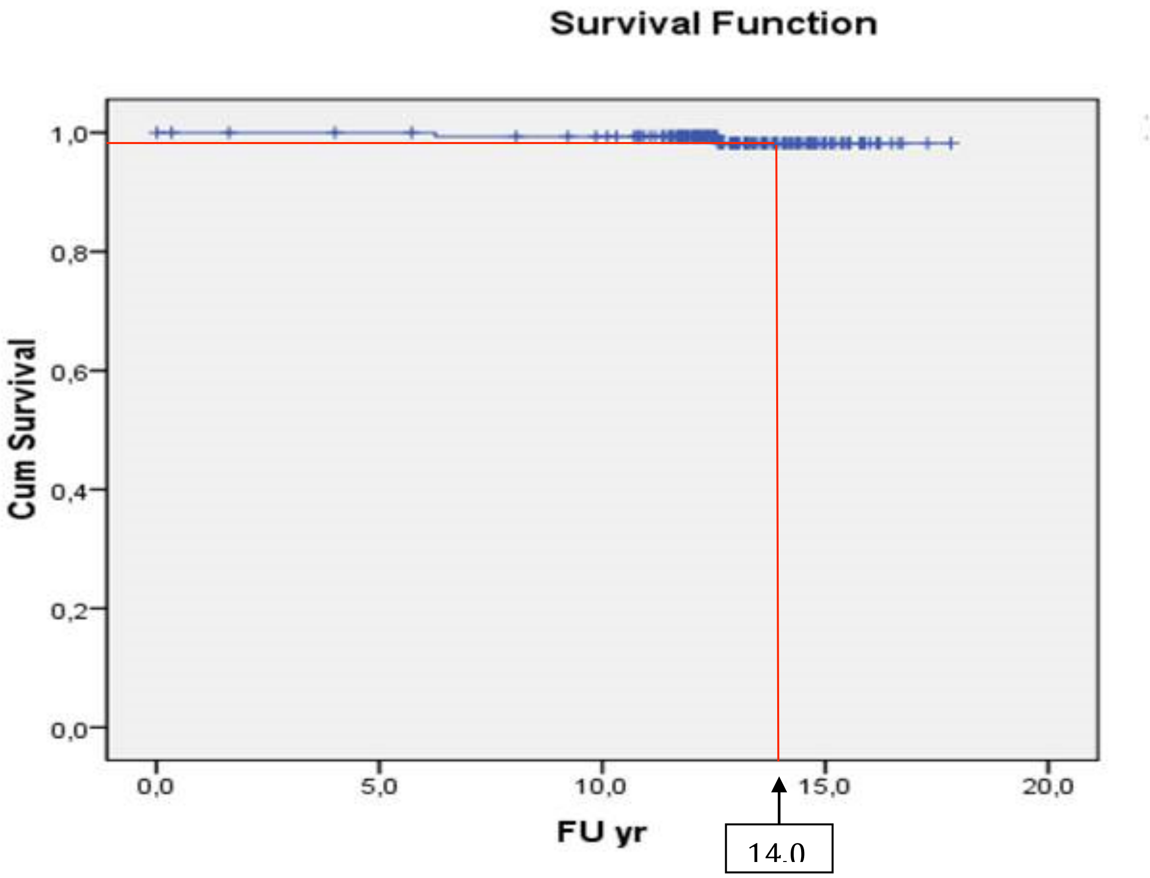

Figure 5: Kaplan-Meier curve for wear of the RM cup and articulation type.

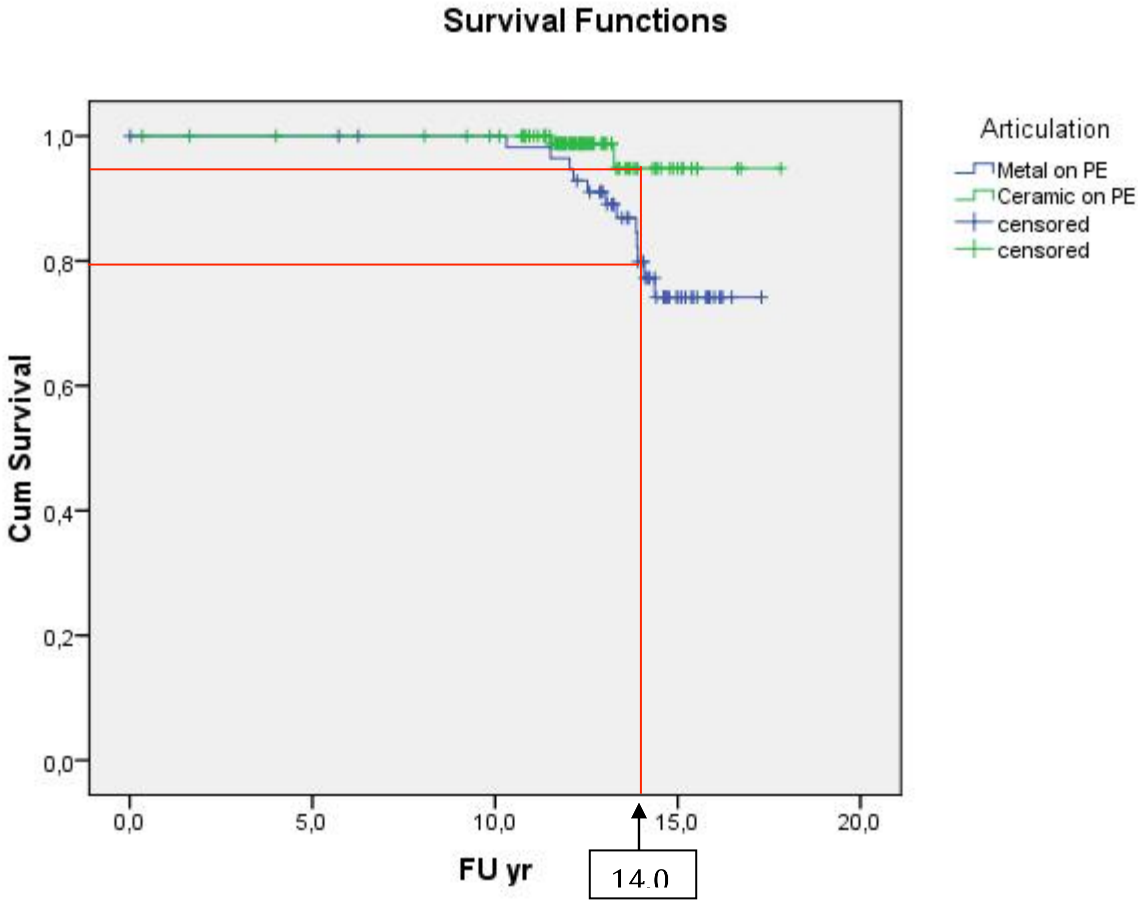

Table 1: Pre operative diagnosis

	Hips (N)
Primary Osteoarthritis	46
Secondary Osteoarthritis	
Rheumatoid disease	29
Hip dysplasia	38
Osteonecrosis	13
Trauma	16
Other causes	16
Total	158

Table 2: Radiologic evaluation

	Non Revised sockets		Revised sockets	
	Post operative	At Follow up	Post operative	Before revision
Patient Numbers	N=130	N=130	N=20	N=20
Inclination (Range)	35° (10-63)	35° (10-60)	37° (18-62)	37° (19-63)
Migration Horizontal		1.9 mm		1.4 mm
Migration Vertical		2.4 mm		1.8 mm
Wear Kang et al (Range)		0.11 mm/yr (0-0.68)		0.16 mm/yr (0.02-0.46)

Table 3: Revision summary

	Age	M/F	Implantation	Indication	Revision	Indication	Articulation	Stem
Case								
1	46	M	23-09-1992	Sec	28-09-1992	Malposition cup	Metal-PE	RM
2	45	M	10-06-1994	Prim	12-10-1994	Malposition cup	Ceramic-PE	CLS
3	43	M	21-04-1992	Sec	09-01-1998	Trauma	Metal-PE	RM
4	46	F	13-01-1993	Sec	15-04-1999	Aseptic loosening	Metal-PE	CLS
5	45	M	17-08-1992	Sec	19-02-2004	Wear $^{\Psi}$	Metal-PE	RM
6	25	M	15-05-1990	Sec	08-04-2004	Wear $^{\Psi}$	Metal-PE	RM
7	40	M	18-01-1994	Sec	10-05-2004	Wear $^{\Sigma}$	Metal-PE	CLS
8	42	F	24-02-1992	Sec	01-01-2005	Trauma	Metal-PE	RM
9	43	F	30-11-1992	Sec	20-01-2005	Wear $^{\Sigma}$	Metal-PE	CLS
10	28	F	19-12-1991	Sec	15-04-2005	Wear $^{\Psi}$	Metal-PE	RM
11	49	M	22-06-1993	Sec	15-09-2005	Trauma	Metal-PE	CLS
12	47	F	22-10-1993	Prim	04-11-2005	Wear $^{\Sigma}$	Metal-PE	CLS
13	29	F	10-11-1992	Sec	23-11-2005	Wear $^{\Psi}$	Metal-PE	RM
14	48	M	21-06-1993	Prim	19-01-2006	Aseptic loosening	Metal-PE	CLS
15	25	F	24-01-1994	Sec	02-08-2006	Wear $^{\Sigma}$	Metal-PE	CLS
16	48	M	04-11-1992	Prim	12-09-2006	Wear $^{\Psi}$	Metal-PE	RM
17	46	M	10-11-1995	Sec	12-09-2006	Trauma	Ceramic-PE	CLS
18	45	M	03-04-1995	Sec	09-10-2006	Wear $^{\Sigma}$	Ceramic-PE	CLS
19	30	F	13-04-1993	Sec	28-02-2007	Wear $^{\Sigma}$	Metal-PE	CLS
20	49	M	16-04-1993	Prim	17-07-2007	Wear $^{\Psi}$	Metal-PE	CLS
21	47	F	28-12-1993	Prim	20-08-2007	Wear $^{\Sigma}$	Ceramic-PE	CLS
22	43	M	16-11-1992	Sec	05-09-2007	Wear $^{\Psi}$	Metal-PE	CLS

Ψ: primary reason for revision is femoral osteolysis with acetabular wear. Σ: Primary reason for revision is acetabular wear.


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Chapter 4:

Acetabular load-transfer and mechanical stability; A finite element analysis comparing different cementless sockets.

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Abstract:

Introduction:
Acetabular stress shielding may be a failure mechanism of acetabular constructs promoting osteolysis, aseptic loosening and failure.
Methods:
We used three-dimensional finite element analysis (FEA) to evaluate the effect of flexible sockets on acetabular stress shielding. The sockets were made of (1) full polyethylene (PE), (2) PE with a metal bearing and (3) a PE insert with a metal backing was used as a traditional stiff implant. We compared the strain energy density and interfacial micro-motions between bone and cementless sockets during walking.
Results:
In our FEA model, the most elastic socket (case 1) showed the highest levels of micro-motion during walking (400 μm). The most rigid socket (case 3) showed smaller areas of high micro-motions. Assuming a threshold for ingrowth of 50 microns, the flexible cup showed an ingrowth area of almost 40%, whereas the two other two cases showed stable areas covering 60% of the total bone-component interface. Furthermore, we found that the introduction of an implant generates a very different strain pattern directly around the implant as compared with the intact case, which has a horse- shoe shaped cartilage layer in the acetabulum. This difference was not affected much by the stiffness of the implant; a more flexible implant resulted in only slightly higher strain levels. Bone strains over 1.5 mm from the cup showed physiological values and were not affected by the stiffness of the implant.
Conclusion:
This study shows that the physiological strain patterns are not obtained in the direct peri-prosthetic bone, regardless of the stiffness of the material.

Introduction:

Total joint replacement may lead to stress shielding of the peri-prosthetic bone. The bone responds to these reduced stress levels by resorption, leading to osteopenia of bone surrounding the implant, in accordance with Wolff's law. [1] Stress shielding has been suggested as a possible failure mechanism in hip arthroplasty and particularly the acetabular component. [2-4] In general, it is thought that by using flexible materials the amount of stress shielding can be reduced. For cemented devices a combination of bone cement and polyethylene is used, whereas for cementless devices a metal backing is often used. As a consequence it can be expected that the stress shielding effect around cementless devices is much higher than around cemented (all-poly) designs. However, currently there are devices on the market which consist of an all-poly monoblock cup and which are suitable for cementless fixation (an example is shown in Figure 1a). Furthermore, cementless PE cups can be provided with a metal inlay, thereby allowing metal-on-metal articulation, but being more flexible at the same time. The philosophy behind these types of designs is that the elastic modulus of the polyethylene socket (approx 1,000 MPa), in contrast to modular metal shells (approx 105,000 MPa), mimics the modulus of the acetabular bone (approx 500-5,000 MPa) much better, resulting in a more physiological distribution of articular stresses, less stress shielding and subsequent bone resorption and thereby creating optimal conditions for long term fixation.

In addition to bone maintenance, long-term fixation of a cementless implant is also affected by its inherent mechanical stability within the bone. A highly stable implant may show early bone ingrowth into the surface of the prosthetic component, whereas unstable components may not allow for adequate osseointegration. Implant stability is affected by design parameters of the acetabular cup. In an earlier study we found that micro-motions at the bone-implant interface could be reduced by increasing interference fit, avoiding low frictional properties and, very important for the current study, not using an implant with a low-stiffness. [5]

Hence, it seems that the aims to achieve long-term bone maintenance and low micro-motions theoretically are incompatible design goals: to reduce stress shielding a flexible cup is required; to reduce micro-motions a stiff cup might be required. The problem of incompatible design goals for orthopaedic implants has been illustrated for the femoral side by Huiskes, [6] but has not been assessed for the acetabular side.

It is clear that the load-transfer mechanism on the acetabular side is different from that of the femoral side, where bending and torque loads play a more significant role. Furthermore, the muscle loads around the acetabulum seem to be much more intense than around the femur, thereby generating a more physiological stress pattern in the bone which is irrespective of the implant type. It is therefore questionable whether the same amount of incompatibility as found for the femoral side is applicable for the acetabular side.

The aim of this study was to analyze the stability and stress shielding effects of three components with varying stiffness properties that are currently on the market and to assess whether design incompatibilities are found similarly to what has been reported on the femoral side. For this purpose micro-motion levels of a press-fit all-poly socket, a press-fit all-poly with a metal inlay and a commonly used, identically shaped, rigid metal backed press-fit socket were quantified using finite element analysis (FEA) techniques and these micro-motion levels were compared with acetabular interfacial micro-motion levels found in literature. To determine the potential advantage of the elastic socket we also evaluated the principle strain and strain energy density (SED) transmission into the acetabular bone for the sockets mentioned above relative to the healthy situation.

Methods:

Interfacial micro-motions

In order to study the effect of material stiffness on micro-motions at the acetabular implant-bone interface, FEA models were created of reconstructions with designs as marketed by Mathys AG, Bettlach, Switzerland. We selected the press-fit RM cup (referred to as all-poly cup), the metal-on-metal RM cup (referred to as the metal inlay cup) and the press-fit metal-backed seleXys cup (referred to as the metal-backed cup). Since the cups all had the same outside geometry, the cup design variations were implemented by changing the material assignment to the various regions of the cup (Figure 2; Table 1). All cups were size 52 and had an inner diameter of 32 mm. Although the RM cups have a titanium coating, it was not modeled as it was assumed to have no structural stiffness. The metal inlay of the metal-on-metal RM cup had a thickness of 4 mm. The titanium shell of the seleXys cup had a thickness varying from 3 to 6 mm (see also Figure 2c).

The cups were introduced into an FEA model of a human pelvis (Figure 3). [7] The acetabulum had an inner diameter of 52 mm. The cups were placed such that the femoral head center was reconstructed, at an inclination angle of 45° and 15° of anteversion. The pelvic model consisted of eight-node brick elements, simulating the trabecular and subchondral bone, and membrane elements to simulate the cortical bone. All implant materials were assumed to be isotropic linear elastic.

The material properties and the thickness of the cortical elements were assessed by quantitative computer tomography according to Kaneko et al. [8] The Young's modulus of the trabecular and subchondral bone ranged from 1 to 2,155 MPa, while the thickness of the cortical layer ranged from 0.7 to 3.2 mm, with an average of 1.5 mm (Table 1). The two pelvic bones forming the pelvis were joined at the pubic symphysis by rigid links. The model consisted of roughly 42,000 elements and 43,500 nodal points.

The press-fit fixation of the implant was modeled using a node-to-surface contact algorithm (MSC. Marc, Santa Ana, CA, USA). At the start of each simulation, an oversized cup was placed in the acetabulum, its elements penetrating the subchondral bone elements. For all cups, the interference fit ranged between 1.5 and 2.0 mm. Subsequently, during a preconditioning phase of three increments, the nodes at the surface of the subchondral bone were automatically 'pulled' towards the cup surface by the contact algorithm. In case of the metal backed cup, the polyethylene liner was assumed to be fixed inside the metal shell. The implant-bone interface was assumed to be debonded. A Coulomb stick-slip model was used to model friction at the bone- implant interface. A friction coefficient of 0.5 applied, which is in the range of friction coefficients for cementless implants. [9]

Upon insertion of the cups the acetabular bone was locally deformed beyond the elastic region. To prevent overestimation of the clamping ability of the acetabulum, plasticity was introduced based on data of Kaneko et al. [8,10] Based upon the Young's moduli given in our pelvic model, the yield stress was calculated for each element of the subchondral bone. The bone material was assumed to be linear elastic-plastic. After yield, the effective stiffness of the material was assumed to be equal to 50% of the initial Young's modulus (Figure 5).

The models were subjected to a loading configuration simulating a cycle of normal walking. [11] The walking cycle was divided in eight different phases (2, 13, 35, 48, 52, 63, 85 and 98% of the walking cycle; Figure 4), during which 21 muscle forces were applied as distributed loads. The hip joint contact force was applied to a spherical rigid body representing the prosthetic femoral head that was in contact with the polyethylene liner. A body weight of 650 N was assumed, in conformance with a previous study by Dalstra and Huiskes. [11] The nodes situated in the sacro-iliac joint areas of both pelvic bones were kept fixed during the simulation.

All models were subjected to two cycles of normal walking. The results presented in this study were collected during the second walking cycle, to allow the cups to settle upon dynamic loading in the first loading cycle.

During the simulations, micro-motions at the implant-bone interface were calculated by tracking the relative sliding velocity of all contact points at the interface (MSC. Marc, Santa Ana, CA, USA). Through integration of the sliding velocity over each increment, the relative displacement between the two contact surfaces (implant and bone) could be established in each contact point. In addition, for each reconstruction we determined the contact area in which the interfacial micro-motions were low enough to allow for bone ingrowth. For this purpose, we tracked the interfacial micro-motions during the entire second walking cycle.

To quantify the potential for ingrowth of the cups we determined the percentage of available ingrowth surface below a certain ingrowth threshold value. The literature is inconclusive about a threshold value, which is why two threshold values were considered below which immediate ingrowth was assumed to occur: either 50 μm, 12 or 150 μm. [13-15]

Load Transfer and Stability of Cementless Acetabular Cups

Acetabular stress distribution

To assess the stress shielding effects of the component configurations we analyzed the stress distribution in the subchondral bone in case of the all-poly cup, the metal-on-metal RM cup, and the seleXys cup relative to the anatomical situation. In the anatomical case a layer of cartilage covering the femoral head, and a horse-shoe shaped layer of cartilage inside the acetabulum was simulated. The thickness of the layer was roughly 0.75 mm, with a very low stiffness (10 MPa) and nearly incompressible material properties. This ensured evenly distributed contact across the joint, while maintaining a numerically stable simulation.

To analyze the strain energy density distribution in the bone, we assumed that in the long term the elevated stress levels caused by the oversized press-fit fixation would be reduced by creep and remodeling. The FEA models were therefore adapted such that a stress-free fixation was achieved. Consequently, no initial residual stresses were present in the reconstruction when unloaded. Furthermore, we assumed a fully bonded implant-bone interface, mimicking an implant that is properly fixated through in- and on growth of bone. These models were again subjected to a load representing a cycle of normal walking, during which we monitored the strain distribution in the subchondral bone and more remote from the cup.

Results:

Interfacial micro-motions

In all models, the largest micro-motions were found during phase 6 of the walking cycle (beginning of the swing phase). The press-fit RM cup displayed the largest micro-motions, with local peaks of up to 400 μm (Figure 6). The micro-motions in the model with the metal-on-metal RM cup had a similar distribution, with lower peak micro-motions (max. 165 μm).

In the model with the seleXys metal-backed implant, the distribution of interfacial micro-motions was somewhat different from that in the RM-cup models. Smaller areas of micro-motions were found, also with lower micro-motions. The peak micro-motion, however, was higher than that in the model with the metal-on- metal RM cup (218 μm in phase 6).

Assuming an ingrowth threshold value of 50 μm, ingrowth could only occur in 39 per cent for the RM-cup (Table 2) of the total contact area between implant and bone. This percentage was increased to almost 60 per cent when a metal inlay was used in this implant. A similar area (about 60%) was obtained with the metal- backed seleXys cup. If a threshold value of 150 μm were chosen, almost 90% of surface would show immediate ingrowth for the RM-cup, whereas the other two-cup designs would show total ingrowth (Table 2).

Analysis of the strain distributions in the subchondral bone showed that in all models the strain distributions were very different from the anatomical case (Figure 7). In the reconstructed cases, the majority of the loads are transferred at the peripheral rim, while in the anatomical case more load is transferred in the center region of the acetabulum.

The all-poly cup seemed to have a bit more load transfer in the center section of the acetabulum compared to the metal inlay or metal-backed cases, but compared to the anatomical case these differences were marginal.

A little further away (>1.5 mm) from the implant-bone interface, the differences between the anatomical case and the implanted cases were negligible, due to the loads exerted by the muscles (Figure 8). Hence, the strains produced by the muscle loads overruled the effect of the differences in cup stiffness and the stimuli for bone remodeling were hardly affected by the different designs at this distance.

Discussion:

The acetabular component in hip arthroplasty has been considered by many as the weak link. [16] The Swedish Hip Arthroplasty Register shows that, although the survival increases with the introduction of modern sockets, acetabular components still compromise the long term survival of total hip arthroplasty. [17]

In their article on stress shielding and the effect of flexible materials, Huiskes et al. stated that when implanting a femoral stem with an elastic modulus similar to cortical bone, the long-term bone loss would decline considerable. [18] A downside of flexible femoral stems is the accompanying high interface micro-motions that result in unsuccessful osseointegration and subsequent loosening. [18] Hence, the incompatibility of bone maintenance and low micro-motions has been highlighted already more than 15 years ago. [6] However, as far as we are aware of, this incompatibility has not been assessed on the acetabular side. For this purpose, we performed an FEA analysis on different types of sockets and determined interfacial micro-motion levels and SED transmissions in this study.

Osseointegration into the porous surface of the acetabular component depends on many factors including primary stability, surface profile, proximity and interfacial micro-motion levels between bone and implant surface. [19-22] In a study performed by Maniatopoulos et al. in 1986, the hypothesis for tolerance levels of micro- motion and ingrowth was confirmed. [23] Animal and in vivo studies investigated the effect of micro-motions on bone in-growth. [13-15] Micro-motions surpassing 150 μm are considered excessive and result in fibrous interposition between implant and bone. Limits of acceptable micro-motions found in literature range between 30 μm and 150 μm. [13-15,22,24]

The FEA method, as used in our study, has been widely accepted as a reliable method to quantify and demonstrate the qualitative effects on interfacial micro-motions. [25-27]
We tried to determine the micro-motions as realistically as possible by including a press-fit situation that creates pre-stresses within the bone as obtained during actual surgery. Furthermore, plasticity of the bone was taken into account, multiple stages within one walking cycle were considered and a preceding 'settling' loading cycle was included during which we noticed that the initial micro-motions were even higher. This settling phenomenon is probably realistic and would also happen during the first loading cycle of a patient, but as it has little relevance to ingrowth we ignored the settling motions in the analyses.

Obviously, the model is subject to a number of limitations such as the fact that we only considered walking as the loading cycle of interest. It is very well possible that other loading configurations containing more extreme loading angles would govern ingrowth. Furthermore, only one implantation situation (bone quality, bone geometry, prosthetic fit, cup position, frictional properties) was simulated, whereas it is known that some of these parameters may affect stability and load-transfer to a considerable level. Due to these limitations, the results can only be interpreted on a qualitative basis.

The peak values of interfacial micro-motion in this study are significantly higher compared with values described in literature. [12,13,15] The highest interfacial micro-motion levels were measured for the press fit RM model, but values for the rigid metal backed sockets were also well in excess of 150 µm. We also noticed a difference in potential ingrowth surface (surface area with micro-motion < 50 µm) between the different types of sockets. The RM press fit model showed the least in growth potential compared to the other socket types. Although our FEA simulations showed high focal interfacial micro-motions and lower in growth potential for an elastic socket the clinical interpretation of these peak values is highly uncertain. Long-term studies concerning elastic cementless sockets provide evidence of excellent long-term fixation and survival. [27] In addition, radiostereometric analysis data measuring stability of the cementless RM press fit socket points towards excellent short-term fixation. [29] Hence, it seems that the human environment tolerates these higher micro-motions of the RM cup very well. The FEA simulations as performed in this study have a shortcoming in the fact that they only consider the direct post-operative situation, whereas ingrowth is a process. We found a 50% surface area of the RM cup with a micro-motion below 50 µm. If this surface would be fixated due to ingrowth the mechanical situation at the interface would be largely different and micro-motions at other areas would also be reduced allowing the ingrowth process to proceed resulting in a more interface extensive ingrowth area. This process could be simulated with iterative computer models but these FEA models should probably be equipped with more clinical ingrowth data.

Attempts have been made to predict tissue ingrowth and differentiation around prosthetic implants, [12,13,28,30] but the validity and applicability of these simulations is debatable and there is a necessity to perform in vivo studies and subsequent simulations of cases in which ingrowth does occur and in cases that ingrowth does not occur.

A few other authors compared rigid with less rigid sockets, [31,32] and showed beneficial effects of non-rigid sockets on the prevention of stress shielding. Meneghini et al. stated that the improved stress transfer could be a result due to the optimized frictional coefficient and conductive surface properties of the tantalum surface. [32] Our study shows that the strains produced directly around the reconstructed cups are remote from the anatomical case. However, the FEA simulations as utilized in this study did not predict the ultimate bone mineral density distribution that can be expected in the future. To allow for this, the FEA models should be expanded with bone remodeling algorithms as utilized for the femoral component, [4,6,18,25,33,34] but as far as we know this has not been applied to predict peri-prosthetic bone remodeling around acetabular components. Again, these predictions should be compared to in vivo data to proof their validity and value for pre-clinical predictions of long-term effects of implant related factors.

What we also found was that the strain distributions in the bone beyond a distance of about 1.5 mm from the cup were not affected by the reconstruction (assuming reconstruction of the anatomical centre). This would mean that mechanically induced bone remodeling takes place at a very small layer of bone surrounding the implant. Obviously, from a fixation point of view, the bone quality of this small region is essential as it is the region where the implant is fixated for a very long period of time. It therefore seems wise to use very small regions of interests that are located close to the implant in in vivo bone remodeling (e.g. DEXA or CT) studies. This furthermore suggests that, in order to more closely analyze the effect of low- stiffness implants on bone remodeling, a denser FEA mesh is required particularly in the implant-bone interface region.

Conclusion:

A finite element investigation of three identically shaped cementless sockets addressing the effect of a changing elastic modulus on interfacial micro-motion level and strain energy density transmission has been presented. We found higher micro-motions around the more flexible implant. Furthermore we found that the introduction of an implant generates a very different strain pattern directly around the implant as compared with the intact case, which has a horse-shoe shaped cartilage layer in the acetabulum. This difference was not much affected by the stiffness of the implant; a more flexible implant resulted in only slightly higher strain levels. Bone strains beyond 1.5 mm from the cup showed physiological values and were not affected by the stiffness of the implant.

We are currently performing CT investigations on cementless elastic sockets, to evaluate bony in growth and peri-prosthetic bone remodeling in vivo.

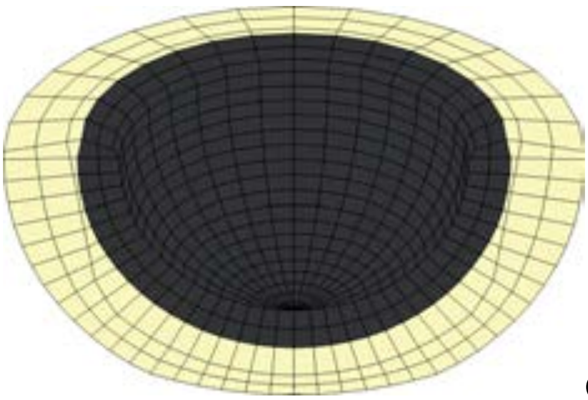
Literature:

1. Wolff J, The Law of Bone Remodeling, Springer, Berlin, 1986.
2. Huo MH, Parvizi J, Bal BS, Mont MA. What's new in total hip arthroplasty. J Bone Joint Surg. 2008;90:2043-2055.
3. Bugbee WD, Culpepper WJ, Engh CA jr, Engh CA sr. Long term clinical consequences of stress shielding after total hip arthroplasty without cement. J Bone Joint Surg. 1997;79:1007-1012.
4. Draenert K, Draenert Y, Kraupse R, Bettin D. Strain adaptive bone remodeling in total joint replacement. Clin Orthop Rel Res. 2005;430:12-27.
5. Janssen D, Zwartele RE, Doets HC, and Verdonschot N. Computational assessment of press-fit acetabular implant fixation: the effect of implant design, interference fit, bone quality, and frictional properties. Proc. IMechE Part H: J. Eng. in Med. 2009;224:67-75.
6. Huiskes R. Stress shielding and bone resorption in THA: clinical versus computer-simulation studies. Acta Orthop Belg. 1993;59:118-129.
7. Dalstra M, Huiskes R, van Erning L. Development and validation of a three-dimensional finite element model of the pelvic bone. J Biomech Eng 117:272-278, 1995.
8. Kaneko TS, Bell JS, Pejcic MR, Tehranzadeh J, Keyak JH. Mechanical properties, density and quantitative CT scan data of trabecular bone with and without metastases. J Biomech. 2004;37:523-530.
9. Dammak M, Shirazi-Adl A, Schwartz M, Jr., Gustavson L. Friction properties at the bone-metal interface: comparison of four different porous metal surfaces. J Biomed Mater Res. 1997;35:329-336.
10. Kaneko TS, Pejcic MR, Tehranzadeh J, Keyak JH. Relationships between material properties and CT scan data of cortical bone with and without metastatic lesions. Med Eng Phys. 2003;25:445-454.
11. Dalstra M, Huiskes R, Load transfer across the pelvic bone. J Biomech. 1995;28:715-724.
12. Spears IR, Ffleiderer M, Schneider E, Hille E, Bergmann G, Morlock M. Interfacial conditions between a press-fit acetabular cup and bone during daily activities: implications for achieving bone in-growth. J Biomech. 2000;33:1471-1477.
13. Pilliar R, Lee J.M, Maniatopoulos DD. Observations on the effect of movement on bone ongrowth into porous-surfaced implants. Clin Orthop Rel Res. 1986;208:108-113.
14. Burke D, O'Conner D, Zalenski E, Jasty M, Harris WH. Micromotions of cemented and cementless femoral components. J Bone Joint Surg. 1991;73:33-37.
15. Szmukler-Moncler S, Salama H, Reingewirtz Y, Dubruille J. The timing of loading and the effect of micro- motion on the dental implant-bone interface; A review of the experimental literature. J Biomed Mat Res. 1998;43:192-203.
16. Corten K, Au K, Bourne R. Acetabular options; notes from the other side. Orthopedics 2009;32(9).
17. Hailer N, Garellick G, Kärrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register. Acta Orthop. 2010;81:34-41.
18. Huiskes R, Weinans H, van Rietbergen B. The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials. Clin Orthop Rel Res. 1992;274:124-134.
19. Søballe K, Hansen E, B-Rasmussen H, Jørgensen P, Bünger C. Tissue ingrowth into titanium and hydroxyapatite-coated implants during stable and unstable mechanical conditions. J Orthop Res. 1992;10:285-299.

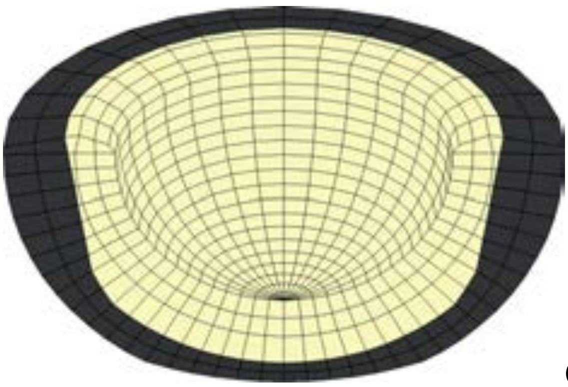
20. Bobyn J, Pilliar R, Cameron H, Weatherly G. The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop Relat Res. 1980;150:263-70.
21. Carlsson L, Röstlund T, Albrektsson B, Albrektsson T. Implant fixation improved by close fit. Cylindrical implant-bone interface studied in rabbits, Acta Orthop Scand. 1988;59:272-275.
22. Pilliar R, Quantative evaluation of the effect of movement at a porous coated implant-bone interface, in Davies (ed.), The bone-biomaterial interface, University of Toronto press, Toronto, pp. 380-387, 1991.
23. Maniatopoulos C, Pilliar R, Smith D. Threaded versus porous-surfaced designs for implant stabilization in bone-endodontic implant model. J Biomed Mater Res. 1986;20:1309-1333.
24. Brunski J. Avoid pitfalls of overloading and micromotion of intraosseous implants. Dent Implantol Update. 1993;4:77-81.
25. Kuiper J, Huiskes R. Friction and stem stiffness affect dynamic interface motion in total hip replacement. J Orthop Res. 1996;14:36-43.
26. Ramamurti B, Orr T, Bragdon C, Lowenstein J, Jasty M, Harris W. Factors influencing stability at the interface between a porous surface and cancellous bone: a finite element analysis of a canine in vivo micromotion experiment. J Biomed Mater Res. 1997;36:274-280.
27. Ihle M, Mai S, Pfluger D, Siebert W. The results of the titanium-coated RM acetabular component at 20 years: a long-term follow-up of an uncemented primary total hip replacement. J Bone Joint Surg. 2008;90:1284-1290.
28. Spears I, Pfleiderer M, Schneider E, Hille E, Morlock M. The effect of interfacial parameters on cup-bone relative micromotions. A finite element investigation. J Biomech. 2001;34:113-120.
29. Pakvis D, Luites J, van Hellemondt G, Spruit M. A cementless, elastic press-fit socket wit hand without screws. Acta Orthop. 2012;83:481-487.
30. Weinans H, Huiskes R, Grootenboer H. Quantitative analysis of bone reactions to relative motions at implant-bone interfaces. J Biomech. 1993;26:1271-1281.
31. Brown T, Poggie R, Pederson D. Finite element analysis of peri-acetabular stress of cemented, metal backed, and porous tantalum backed components. Trans Orthop Res Soc. 1999;24:747.
32. Meneghini R, Ford K, McCollough C, Hanssen A, Lewallen D. Bone remodeling around porous metal cementless acetabular components. J Arthroplasty. 2010;25: 741-747.
33. Weinans H, Sumner D, Igloria R, Natarajan R. Sensitivity of periprosthetic stress-shielding to load and the bone density-modulus relationship in subject-specific finite element models. J Biomech. 2000;33:809-817.
34. Scannell P, Prendergast P. Cortical and interfacial bone changes around a non-cemented hip implant: simulations using a combined strain/damage remodeling algorithm. Med Eng Phys. 2009;31:477-488.

Figure 1.RM press-fit cup (a), the metal-on-metal RM cup (b) and the metal-backed seleXys cup (c).

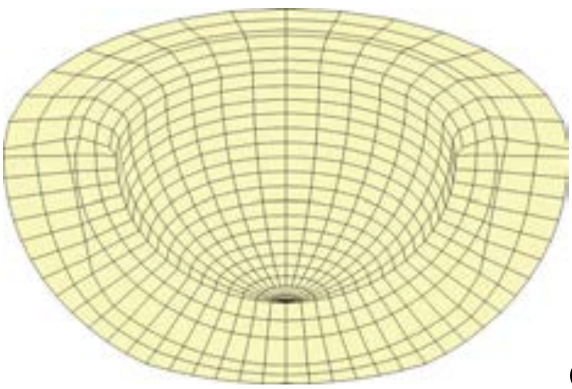
Figure 2 Finite element models of the press-fit RM cup (a), metal-on-metal RM cup (b), and the seleXys cup (c).



(a)



(b)



(c)

Figure 3 Finite element model of a reconstruction with a metal-backed press-fit cup in the human pelvis.

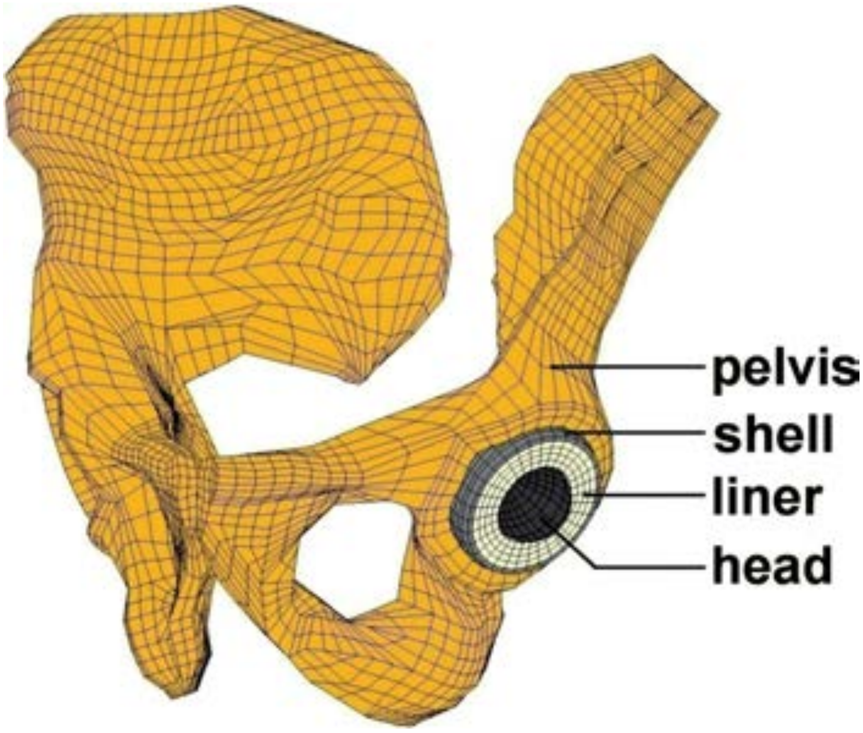


Figure 4 Plasticity curve used for the subchondral bone.

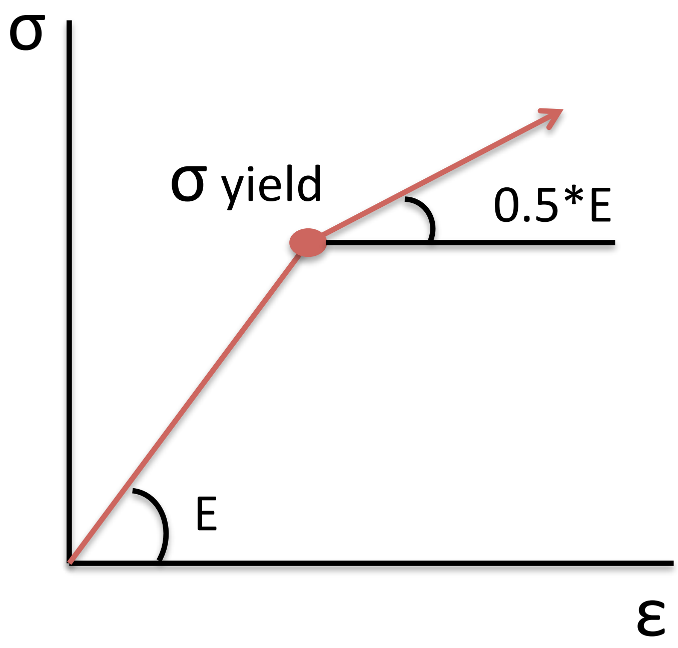


Figure 5 Eight phases of the walking cycle that were analyzed in the current study.

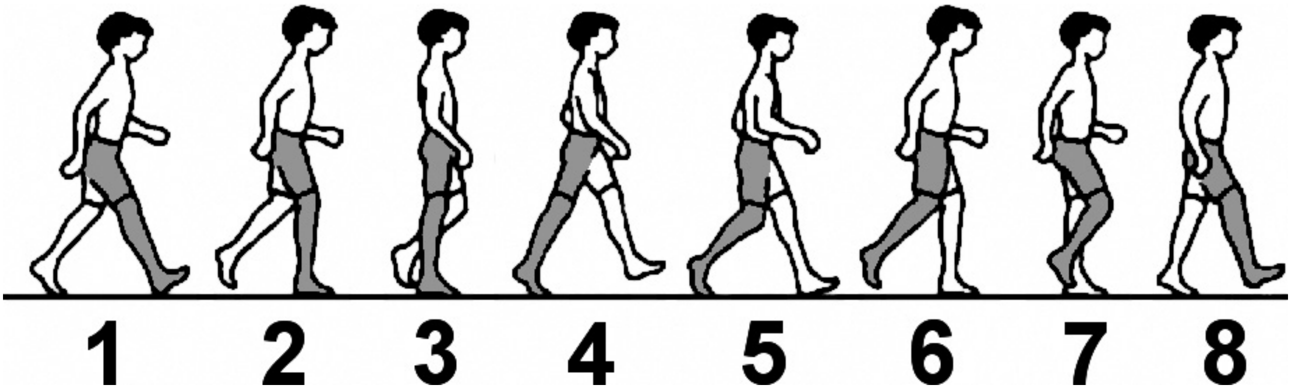


Figure 6 Maximum principal stress in the models with the all-poly, metal inlay and metal-backed implants during the walking cycle.

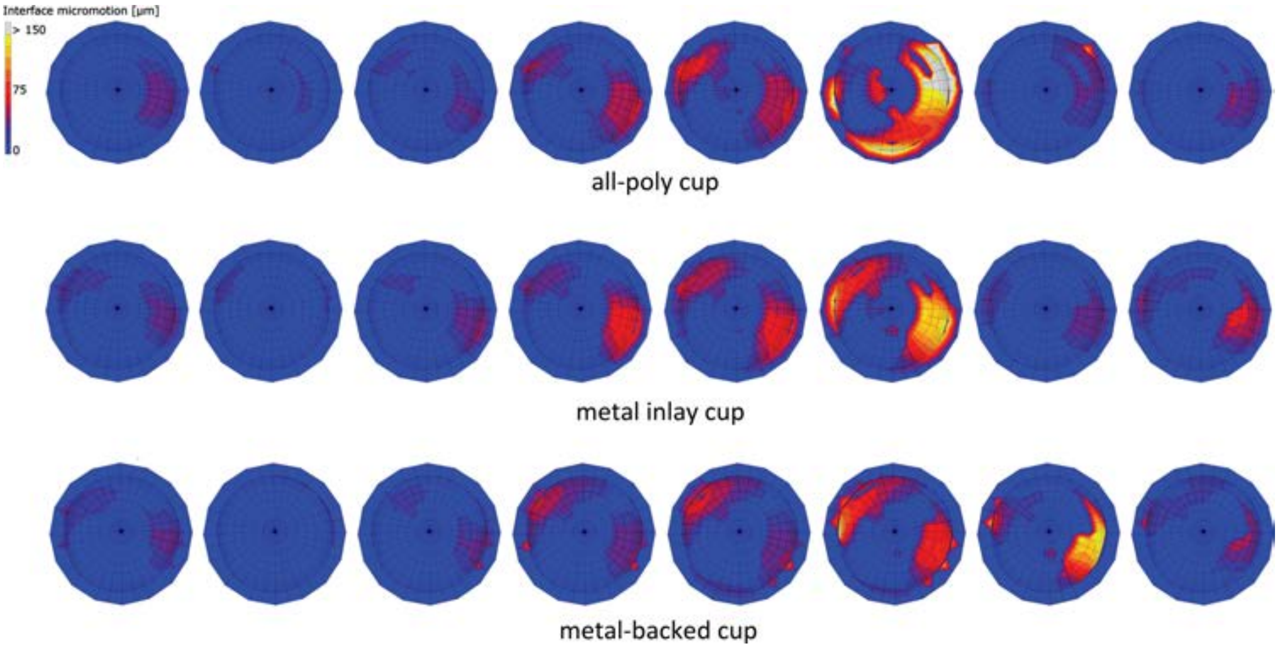


Figure 7 Principle strain distribution in the various models during the eight phases of the walking cycle. Note the different scale for the implanted cases; in these cases the majority of the load was transferred at the rim of the acetabulum.

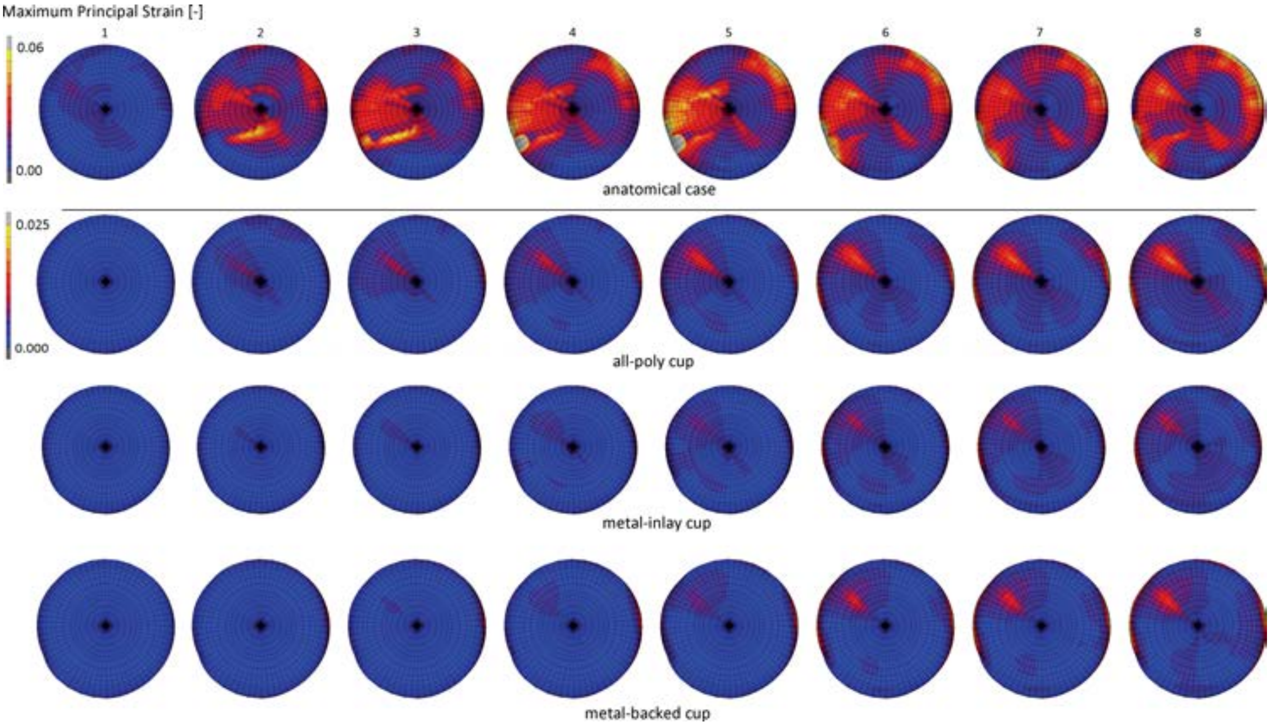


Figure 8 Accumulated strain energy density distribution after the walking cycle. Cross sections are shown at different levels with respect to the hip joint center, from distally to proximally (31.25 to þ31.25 mm).

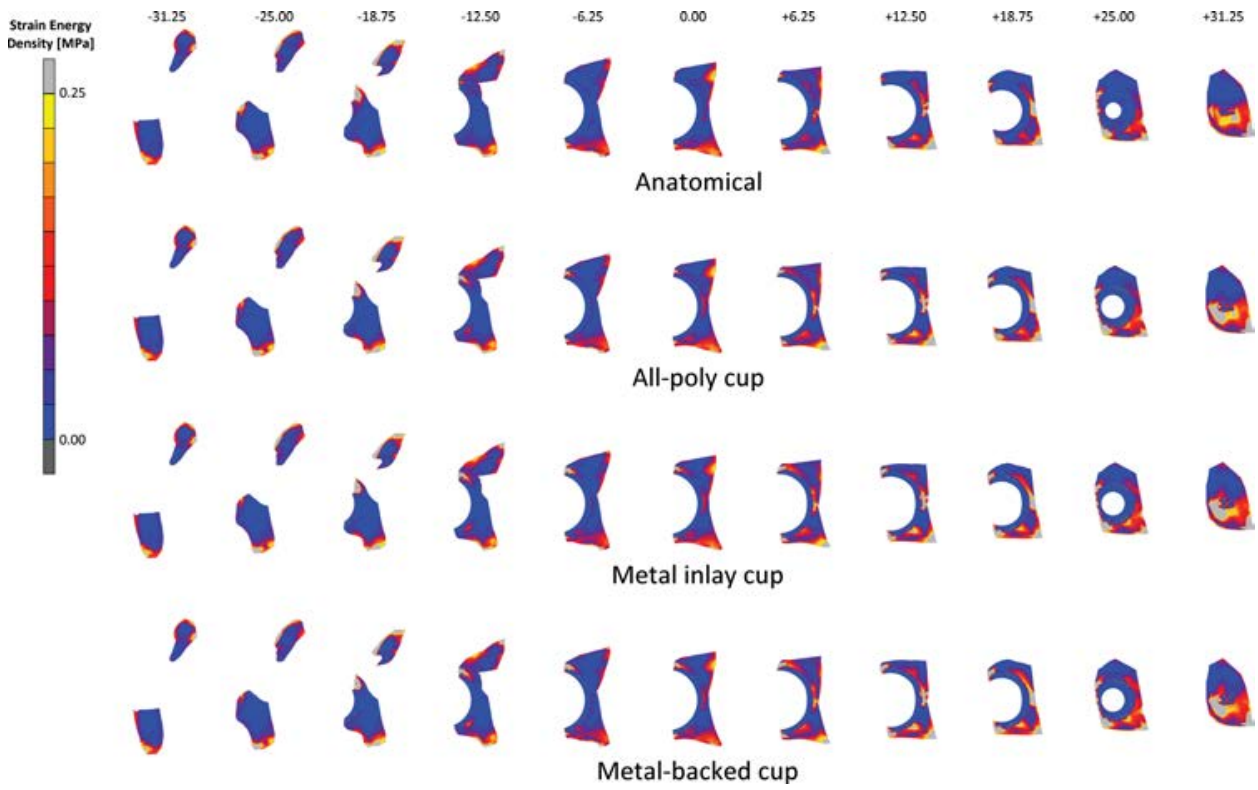


Table 1 Material properties used in the FEA models

		Young's Modulus (Mpa)	Poisson's ratio (-)
Pelvis	Cortical bone	17,000	0.3
	Trabecular bone	1 to 132	0.2
	Subchondral bone	186 to 2,155	0.2
Implant	Polyethylene	700	0.45
	Shell	110,000	0.3
	Bone cement	2,800	0.3

Table 2 Initial area of potential ingrowth (area with initial interfacial micro-motions smaller than either 40 µm or 150 µm)

Implant design	Potential ingrowth area With a threshold of 40 µm (% of total cup area)	Potential ingrowth area With a threshold of 150 µm (% of total cup area)
RM-cup	38.99	88.67
RM-cup (Metal –on-Metal)	58.09	99.73
SeleXys (Metal-backed)	55.54	99.45

Chapter 5:

A cementless, elastic press-fit socket with and without screws: A 2-year randomized controlled radiostereometric analysis of 37 hips.

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Abstract:

Introduction:
The acetabular component has remained the weakest link in hip arthroplasty to achieve long-term survival. Primary fixation is a prerequisite for long-term performance. For this reason we investigated the stability of a unique cementless titanium coated elastic monoblock socket and the influence of supplementary screw fixation.
Patient and methods:
During 2006 – 2008 we performed a randomized controlled trial on 37 patients (mean age 63 years SD 7, 22 females) in whom we implanted a cementless press-fit socket. The socket was implanted with additional screw fixation (Group A, n= 19) and without additional screw fixation (Group B, n= 18). Using radiostereometric analysis with a 2-year follow-up, we determined the stability of the socket. Clinically relevant migration was defined as >1 mm translation and >2º rotation.
Results:
The sockets without screw fixation showed a statistically significant higher proximal translation compared with the socket with additional screw fixation. However this higher migration was below the clinically relevant threshold. The numbers of migratory sockets were not different between both groups. After 2-year follow-up there were no clinical relevant differences between group A and B regarding the clinical scores. One patient dropped out of the study; we had no socket revisions.
Conclusion:
We found that additional screw fixation is not necessary to achieve stability for the cementless press-fit elastic RM socket. We saw no postoperative benefit or clinical effect of additional screw fixation.

Introduction:

During the last 5 years, several long-term reports on different methods to achieve primary stability in cementless sockets have shown excellent survival using aseptic loosening as the end point. [Kim 2005, Kim et al. 2005, Firestone et al. 2007, Suckel et al. 2009, Pakvis et al. 2010]
During the last 2 decades, we have used the cementless RM classic socket with good to excellent long-term results. [Diks et al. 2005, Pakvis et al. 2011] Ihle et al. [2008] also reported good long-term results for this cementless, titanium particle coated socket. This socket is based on the philosophy that an elastic polyethylene RM socket (approx 1000 N/mm2), in contrast to a Titanium Calcium Phosphate rigid metal shell (approx 105,000 N/mm2), provides the elastic properties of acetabular bone (approx 500-6000 N/mm2). The resulting physiological distribution of articular forces protects the acetabular bone and provides optimal conditions for ingrowth, with subsequent long-term component fixation. Due to stress shielding, rigid sockets may decrease the acetabular bone quality. [Huo et al. 2008, Wright et al. 2001] In comparison to femoral stress shielding, acetabular stress shielding results in osteolysis and component migration requiring revision surgery.
The primary stability of the RM classic socket is achieved by 2 pegs and additional screw fixation; Secondary stability is achieved by biological ingrowth into the titanium particle coating. At our specialized orthopedic training hospital, we have encountered implantation difficulties, which led to a learning curve for optimally positioning the pegs. In a primary series this resulted in malpositioning of the socket and a high rate of early to short-term revisions. [Diks et al. 2005] The new design of the peg-less, titanium crews to the primary stability of press-fit sockets. [Hadjari et al. 1994, Thanner et al. 1996] When additional screw fixation is used, some potentially negative effects for the long-term survival have to be accepted. The development of osteolytic lesions is believed to be the resultof the transmission of articular pressure and of wear particles into the acetabular bone via the screw channels. [Schmalzried et al. 1997]
To our knowledge only Thanner et al. [2000] performed a RSA randomized controlled trial (RCT) that showed no effect of the additional screw fixation in a rigid metal-backed modular titanium meshed HA (hydroxyapatite) coated socket.
We performed an RCT to evaluate the stability of the cementless, RM press-fit socket with and without additional screw fixation. We used radiostereometric analysis (RSA) to determine the stability in each group. We hypothesized difference in stability between the cementless RM press-fit sockets with and those without additional screw fixation: due to the elastic modulus of the RM press-fit socket without additional screw fixation, a larger migration would occur shortly after surgery but that would stabilize during the two-year follow-up.

Methods:

This study was performed in compliance with the Helsinki declaration for medical research involving human subjects. It is a single-centre, equally randomized, parallel-grouped study, conducted between 2006 and 2008 at the Sint Maartenskliniek Nijmegen. It was approved by the local ethical committee (reg. no 2006032). Patients were followed for 2-years. Randomization was done prior to the start of the trial using a computer-generated random patient allocation in blocks of four, per participating surgeon (Block Stratified Randomization version 4.4, 1997, S. Piantadosi, Baltimore, Maryland). Only after the implantation of the socket, the participating surgeons were informed through a closed envelop of the allocated treatment. Inclusion criteria were unilateral primary osteoarthritis, BMI < 30, age between 18- 70 years and written informed consent. Patients with secondary osteoarthritis and pregnancy were excluded from this study.

Surgical technique

All hips were implanted by the two senior authors (GvH, MS). Preoperative, prophylactic third generation cephalosporins were given to all patients. All arthroplasties were performed using a posterolateral approach in a clear-air operation theatre with laminar flow. Reaming of the acetabulum was undersized by 1.6 mm to achieve adequate press-fit. The RM press-fit socket (Mathys Ltd, Bettlach) is an all polyethylene socket with a titanium particle coating. The socket has a hemispherical monoblock design with a flatted pole and is made from nitrogen-radiated sterilised UHMW (ISO 5834-1+2) polyethylene.
For additional fixation (when performed), two 4.0 mm screws of variable length were placed through two of the four screw openings situated in the sockets rim. A cementless, grit-blasted, titanium alloy (Ti6Al4V ISO 5832-3) CLS Spotorno femoral stem (Zimmer, Warsaw Inc.) was used in all cases. In all patients a 32 mm ceramic (Al_2O_3) head on polyethylene articulation was used.
All patients were mobilized on the first postoperative day and direct full weight bearing was allowed using crutches during the postoperative rehabilitation period that was supervised by a physiotherapist. All patients received nadoparine for 6 weeks as tromboprofylaxis.

Radiostereometric analysis

6 tantalum, 1.2 mm markers were inserted preoperatively into pre-existing openings in the polyethylene rim of the RM press-fit socket using a specially developed insertion system (Mathys Ltd, Bettlach, Switzerland) (Figure 2). During the operation, markers with a 0.8 mm diameter were inserted into the acetabular bone after the acetabulum had been reamed to the required diameter. A minimum of 6 markers were inserted using an insertion gun, at a 10 mm depth in all regions of the acetabular bone resulting in scattered positions to fulfil the conditions for accurate RSA measurements (Mathys Ltd, Bettlach, Switzerland). During the first postoperative week, baseline digital RSA radiographs (Figure 3) were taken (Agfa-Gevaert AG, Rijswijk, The Netherlands). Follow-up images were taken during the outpatient clinic visit at 2, 6, 12, and 24 months. A calibration cage (Medis, Leiden, The Netherlands) was placed beneath the patient as described by Selvik (1990). All RSA radiographs (165 dpi and 11-bit grey scale resolution) were analyzed by using RSA-CMS software (version 4.3, Medis, Leiden, The Netherlands). Upper limits for errors were set to maintain RSA measurement quality; for transformation errors at 0.2, for focus errors at 2.0 and for the crossing errors of 2 connected markers at 0.15. For the rigid body errors the limit was set at 0.5, however most of the time the error was below 0.3 for the cup as well as the bone. Unstable markers (>0.3 mm change in distance in consecutive radiographs) were excluded from analysis by the software. Finally, we double-checked measurements from which migration appeared, to be sure that this was not caused by a measurement error.
Migration was defined as micromotion of the centre of gravity of the RM cup relative to the acetabular bone in the 3 translational and 3 rotational directions (Vrooman et al. 1998, Valstar et al. 2005). The precision of the RSA analysis was assessed using double examinations in all patients at the 2-month follow-up; the second set was made after complete repositioning of the patient and equipment. The differences in migration between the double radiographs, 30 for translational directions and 29 for rotational directions, were used to calculate the migration detection limits according to the Bland-Altman method (Table 2). Migration was calculated between the postoperative baseline moment and each follow-up moment at 2, 6, 12 and 24 months.

Clinical outcome

The Harris Hip score (HHS) and the Oxford hip questionnaire were determined preoperatively and at each follow-up. All adverse events and complications were recorded and analyzed to monitor the safety of the technique used.

Statistics

An a priori calculation with a significance level of 0.05, 90% power and standard deviations of 0.4 mm (translation) and 0.9° (rotation) (Röhrl et al. 2004) indicated that 17 persons per group were needed to detect a significant migration difference of 0.4 mm or 0.9° between the groups. At each follow-up, mean migration for the 3 translations and the 3 rotations were determined as well as the SD and minimums and maximums.
To test our hypothesis, we needed to compare the migration patterns of the 2 groups. However, because of the multiple primary endpoints (3 translations and 3 rotations to describe a 3-dimensional migration measured at 4 follow-up moments) and the small sample size, we could not construct a mathematical model. Therefore, we used a repeated measure ANOVA (analysis of variance) for each individual translation and rotation parameter, with time as the within-subject factor and with/without screws as between subjects factor. Post hoc, Scheffe's test was used to identify follow-up moments in which the migration pattern was different between the groups.

Since, to our knowledge, no clinical relevant migration values for uncemented cups are availabe in the literature, we arbitrarily defined a translation of > 1 mm and/or a rotation of > 2º as being clinically relevant. The numbers of sockets with migration above those thresholds were counted for each group and a X^2-test was used to determine whether there was a statistical difference between the groups.
The clinical scores were evaluated; using the Mann-Whitney U test to compare the preoperative as well as the postoperative (2-years) clinical scores between the groups.
Statistical analyses were performed using SPSS and p values <0.05 were considered as statistically significant.

Results:

45 patients were assessed for eligibility in this prospective study. 6 patients declined to participate. During the preparation for surgery, the sets used to place the tantalum markers were not available for 2 patient and these patients could not be enrolled. The remaining 37 enrolled patients (mean age 63 years, SD 7, 22 females) were not informed about the allocation result. Group A consisted of 19 patients (11 females) treated without the additional screw stabilization. In group B, the 18 patients (11 females) received additional screw fixation (Figure 4, CONSORT flow chart). The study demographics are presented in Table 2.

Radiostereometric analysis

The repeated measures ANOVA revealed statistically significantly more proximal-distal translation for the group without additional screw fixation (p=0.04) (Figure 5). Although this effect was consistent at all follow-up evaluations, the mean translation remained well below the defined clinically relevant migration threshold of 1 mm (Table 3). No other statistically significant differences in fixation could be found for the medial-lateral and anterior-posterior translations or for the 3 rotation parameters.
At the 2- and 24- month follow-up the numbers of sockets migrating more than the predetermined clinically relevant threshold did not differ between the groups (p=0.2 at both followup-moments). In group B (with screws), zero sockets showed migration values more than the considered clinically relevant tresholds. The 2 sockets from group A (without additional screw fixation) which showed migration above the predetermined clinically relevant threshold at 2 months had stabilized by the later follow-up assessments. At 2 years, 2 other sockets from group A showed migration that exceeded the clinically relevant values: 1 socket showed a proximal translation slightly more than 1 mm and a second socket showed a retroversion of 2.2º (Figure 5).

Clinical results

The preoperative Harris Hip score and the Oxford hip questionnaire did not differ between the 2 groups (Table 4). At 2 years, there was no statistically significant difference between the groups in either clinical score (p=0.05 for HHS score and p=0.4 for Oxford score).

Adverse events

None of the implanted sockets were revised. 1 patient (with the additional screw fixation) dropped out of the study due to terminal prostate cancer; the radiographical and clinical assessments at 1 year showed no complications. 2 femoral revisions dislocations were performed. Both showed no clinical relevant socket migration at the 2-year follow-up, although the patient with the peri prosthetic fracture had persistent thigh pain resulting in a poor clinical result.
1 patient underwent an additional operation at 3 months due to a deep infection treated within 6 weeks of the primary operation with lavage and appropriate culture-guided antibiotic. At the 2-year follow-up, migration analysis showed a stable socket; the clinical scores were excellent. Another patient sustained a neuropraxia of the sciatic nerve due to a postoperative hematoma. A surgical evacuation of the haematoma resulted in full remission of the clinical symptoms. At the last follow-up, both RSA and clinical scores showed excellent results. 2 other patients complained of mild thigh pain without socket migration or scintigrafic signs of complications.

Discussion:

We found a statistically significant but clinically non-relevant higher proximal migration in the RM press-fit sockets without additional screw fixation. This proximal translation was detected during the settling phase of the press-fit socket at the 2-month follow-up after which no additional statistically significant migration was seen. There was no statistically significant difference in the distribution of sockets showing migration above the clinically relevant threshold between the 2 groups. Hereby, our hypothesis could be confirmed that, although additional screw fixation resulted in direct stability of the socket during the first 2 months, also without additional screws the press-fit RM cup becomes a stable socket after the settling phase, with migrations remaining below the clinical relevant threshold (>1 mm translation, >2° rotation).
Radiostereometric analysis is a sensitive predictor for the long-term stability for arthroplasties. [Karrholm et al. 1994, Ryd et al. 1995, Rohrl et al. 2006, Derbyshire et al. 2009] In particular RSA has demonstrated the stability of acetabular components in total hip arthroplasty. [Nivbrant et al. 1996, 1997, Onsten et al. 1996, Thanner et al. 2000, Rohrl et al. 2004, Digas et al. 2004, Zhou et al. 2006] However, we have not found any article reporting the effect on stability of additional screw fixation for the cementless, elastic press-fit socket. Our study supports the proposed potential advantage of the titanium particle coated, cementless, elastic, monoblock. This construction seems to promote osseointegration of the titanium particle coating without affecting the elastic properties of the socket. Thus it permits transmission of the physiological articular stresses, thereby reducing acetabular stress shielding and the development of acetabular osteolysis. In an unpublished, finite element study we have found high interfacial micromotions between the acetabular bone and the RM press-fit socket. This could be explained due to the elastic modulus of both the acetabular bone and the RM press-fit socket. Sufficient reduction of interfacial micromotions is necessary to produce adequate bone ingrowth and to achieve stability.

In vitro and computer analysis studies have reported ambiguous views concerning the necessity of additional screw fixation. [Won et al.1995, Hsu et al. 2006, 2010] While the present study has found an initial statistically significant proximal migration for sockets implanted without additional screw fixation, this effect remained well below the clinically relevant level. We attribute this minimal migration during the early postoperative period to the socket settling itself into the reamed acetabular bone. This has also been reported by Thanner et al [2000] who postulated that the placement of additional screws could compromise the required settling of the implant that is beneficial for the biological ingrowth when using a press-fit, metal-backed socket as did Rohrl et al. [2004] Schmalzried had already noted the settling along the vector line of the hip joint reaction force in 1994. [Schmalzried et al. 1994)] In addition, other authors have reported the advantages and disadvantages of additional screw fixation in cementless sockets. [Perona et al. 1992, Huk et al. 1994, Barrack et al. 1997, Hsu et al. 2007)]

Recently Zilkens et al. [2011] used Ein Bild Radiographic Analysis (EBRA) to show that there was no effect when using additional screw fixation in rigid cementless press-fit sockets.

The values found in this study for the mean translations (<0.3 mm) and the mean rotations (<0.4°) in each directions for both groups are comparable to or below the migration values found in other RSA studies for sockets with or without additional fixation and with different surfaces. [Onsten et al. 1995, Zhou et al. 2006, Onsten et al.1996, Thanner et al. 2000, Rohrl et al. 2004)]

Multiplicity concerns could be raised when interpreting our results. Migration of a socket is a 3-D process that for explanatory purposes has been determined in 2-D planes between or around the x, y and z-axes. When conducting statistical analyzes on RSA-data, one should keep in mind that translation found within a plane defined by 2 axes, per definition defines the translation along the third axis. As a larger sample size was not possible for practical reasons, we used a repeated measure ANOVA to correct for multiplicity. Another limitation in interpreting the results of hip arthroplasty RSA studies are the clinically relevant RSA migration values. In this study the clinically relevant thresholds were based on the experience of orthopedic surgeons performing more than 100 total hip arthoplasties a year.

Based on our data, this cementless press-fit elastic socket with a ceramic on PE articulation, without additional screw fixation could have a long-term survival and has the qualities to reduce the potentially clinically relevant acetabular stress shielding as described in Wolff's law. We are performing further clinical studies using quantative CT (Computer Tomography) bone mineral density measurements to evaluate the long-term effect of socket elasticity on acetabular bone quality.

In conclusion, we found a statistically significant proximal translation of the press-fit sockets without the additional screw fixation that was well below our clinically relevant threshold for migration. However, this migration appeared during the settling phase in the first 2 months postoperative, after that period the sockets became stable. We therefore see no benefit from additional screw fixation for this cementless, elastic press-fit socket.

Literature:

1. Barrack R, Folgueuras A, Munn B, Tvetden D, Sharkey P. Pelvic osteolysis and polyethylene wear at 5-8 years in an uncemented total hip. Clin Orthop Rel Res. 1997:335;211-7
2. Derbyshire B, Prescott R, Porter M. Notes on the use and interpretation of radiostereometric analysis. Acta Orthop. 2009:80;124-30.
3. Digas G, Thanner J, Anderberg C, Karrholm J. Bioactive cement or ceramic/porous coating vs conventional cement to obtain early stability of the acetabular cup. Randomised study of 96 hips followed with radiostereometry. J Orthop Res. 2004:22;1035-43.
4. Diks M, van den Broek CM, Anderson PG, van Limbeek J, Spruit M. The uncemented, titanium coated RM cup: Survival and analysis of failures. Hip Int. 2005; 15: 71-77.
5. Firestone D, Callaghan J, Liu S, Goetz D, Sullivan P, Vittetoe D, Johnston R. Total hip arthroplasty with a cemented, polished femoral stem, and a cementless acetabular component. A follow-up study at a minimum of ten years. J Bone Joint Surg. 2007:89;126-32.
6. Hadjari M, Hollis J, Hofmann O, Nelson C. Initial stability of porous coated acetabular implants. The effect of screw placement, screw tightness, defect type, and oversize implants. Clin Orthop Rel Res. 1994:307;117-23.
7. Hsu J, Lai K, Chen Q, Zobitz M, Huang H, An K, Chang C. The relation between micromotion and screw fixation in acetabular cup. Comput Methods Programs Biomed. 2006:84;34-41.
8. Hsu J, Chang C, Huang H, Zobitz M, Chen W, Lai K, An K. The number of screws, bone quality, and friction coefficient affect acetabular cup stability. Med Eng Phys. 2007:29;1089-95.
9. Hsu J, Lin D. Effects of screw eccentricity on the initial stability of the acetabular cup in artificial foam bone of different quality. Artif Organs. 2010:34;E10-6.
10. Huk O, Bansal M, Betts F, Rimnac C, Lieberman J, Huo M, Salvati E. Polyethylene and metal debris generated by non-articulating surfaces of modular acetabular components. J Bone Joint Surg.1994:76;568-74.
11. Huo MH, Osier CJ. Is cement still a fixation option for total hip arthroplasty? J Arthroplasty 2008:23:51-4.
12. Ihle M, Mai S, Pfluger D, Siebert W. The results of the titanium-coated RM acetabular component at 20 years: a long-term follow-up of an uncemented primary total hip replacement. J Bone Joint Surg. 2008: 90:1284-90.
13. Iorio R, Puskas B, Healy W, Tilzey J, Specht L, Thompson S. Cementless acetabular fixation with and without screws. J Arthroplasty. 2010:25;309-13.
14. Kim Y. Long-tern results of the cementless porous-coated anatomic total hip prosthesis. J Bone Joint Surg. 2005:87;623-7.
15. Kim YG, Kim SY, Kim SJ, Park BC, Kim PT, Ihn JC. The use of cementless expansion acetabular component and an alumina-polyethylene bearing in total hip arthroplasty for osteonecrosis. J Bone Joint Surg. 2005:87:776-80.
16. Nivbrant B, Karrholm J, Onsten I, Carlsson A, Snorrason F. Migration of porous press-fit cups in hip revision arthroplasty. J Arthroplasty. 1996:11;390-96.
17. Nivbrant B, Karrholm J. Migration and wear of hydroxyapatite-coated press-fit cups in revision hip arthroplasty. A radiostereometric study. J Arthroplasty. 1997:12;904-12.
18. Onsten I, Carlsson A, Sanzen L, Besjakov J. Migration and wear of a hydroxyapatite-coated hip prosthesis. J Bone Joint Surg. 1996:78;85-91.
19. Ornstein E, Franzen H, Johnsson R, Stefansdottir, Sundberg M, Tagil M. Five-year follow up of socket movements and loosening after revision with impacted morselized allograft bone and cement. J Arthroplasty. 2006:21;975-84.

20. Pakvis D, Biemond L, van Hellemondt G, Spruit M. A cementless elastic monoblock socket in young patients: a ten to 18-year clinical and radiological follow-up. Int Orthop. 2011;35:1445-51.
21. Perona P, Lawrence J, Paprosky W, Patwardhan A, Sartori M. Acetabular micromotion as a measure of initial implant stability in primary hip arthroplasty. An in vitro comparison of different methods of initial acetabular component fixation. J Arthroplasty. 1992:7;537-47.
22. Rohrl A, Nivbrant B, Strom H, Nilsson K. Effect of augmented cup fixation on stability, wear, and osteolysis. A 5-year follow up of total hip arthroplasty with RSA. J Arthroplasty. 2004:19;962-71.
23. Rohrl S, Nivbrant B, Snorrason F, Karrholm J, Nilsson K. Porous coated cups fixed with screws. A 12 year clinical and radiostereometric follow up of 50 hips. Acta Orthop. 2006:77;393-401.
24. Roth A, Winzer T, Sander K, Anders J, Venbrocks. Press fit fixation of cementless cups: how much stability do we need indeed? Arch Orthop Trauma Surg. 2006:126;77-81.
25. Ryd L, Albrektsson B, Carlsson L, Dansgard F, Herberts P, Lindstrand A, Regner L, Toksvig--Larsen S. J Bone Joint Surg. 1995:77;377-83.
26. Schmalzried T, Akizuki K, Fedenko A, Mirra J. The role of access of joint fluid to bone in periarticular osteolysis. A report of four cases. J Bone Joint Surg. 1997:79;447-52.
27. Schmalzried T, Wessinger S, Hill G, Harris W. The Harris-Galante porous acetabular component press-fit without screw fixation. Five-year radiographic analysis of primary cases. J Arthroplasty. 1994:9;235-42.
28. Selvik G. Roentgen stereophotogrammetric analysis. Acta Radiol. 1990:31;113-26.
29. Suckel A, Geiger F, Kinz L, Wulker N, Garbrecht M. Long term results for the uncemented Zweymuller/alloclassic hip endoprosthesis. A 15-year minimum follow-up of 320 hip operations. J Arthroplasty. 2009:24;846-53.
30. Thanner J, Karrholm J, Malchau H, Wallinder L, Herberts P. Migration of press-fit cups fixed with poly-l-lactic acid or titanium screws: A randomized study using radiostereometry. J Orthop Res. 1996:14;895-900.
31. Thanner J, Karrholm J, Herberts P, Malchau H. Hydroxyapatite and tricalcium phosphate-coated cups with and without screw fixation. A randomized study of 64 patients. J Arthroplasty. 2000:15;405-12.
32. Valstar ER, Garling EH, Rozing PM. Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis 21 elbows followed for 2 years. Acta Orthop. 2002:73;264-72.
33. Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop. 2005; 76:563-572.
34. Vrooman HA, Valstar ER, Brand GJ, Admiraal DR, Rozing PM, Reiber JH. Fast and accurate automated measurements in digitized stereophotogrammetric radiographs. J.Biomech. 1998;31:491-498.
35. Won C, Hearn T, Tile M. Micromotion of cementless hemispherical acetabular components. Does press-fit need adjunctive screw fixation. J Bone Joint Surg. 1995:77;484-9.
36. Wright JM, Pellicci PM, Salvati EA, Ghelman B, Roberts MM, Koh JL. Bone density adjacent to press-fit acetabular components. A prospective analysis with quantitative computed tomography. J Bone Joint Surg. 2001:83:529-36.
37. Zhou Z, Li M, Borlin N, Wood D, Nivbrant B. No increased migration in cups with ceramic-on-ceramic bearing. An RSA study. Clin Orthop Rel Res. 2006:448;39-45
38. Zilkens C, Djalali S, Bittersohl B, et al. Migration pattern of cementless press fit cups in the presence of stabilizing screws in total hip arthroplasty. Eur J Med Res. 2011:28;127-32.

Figure 1 The cementless titanium particle coated RM press-fit socket.

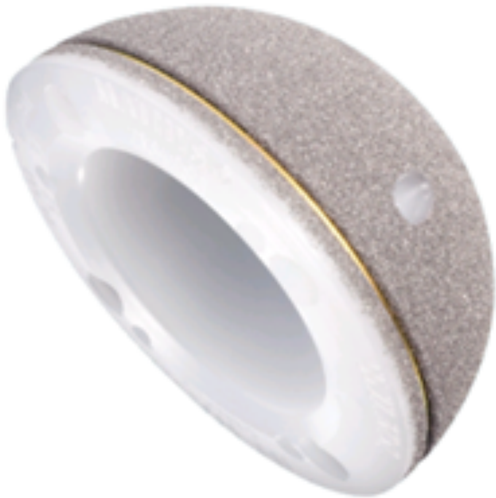

Figure 2 The RM press-fit socket with six tantalum markers (1.2 mm) inserted into pre-existing openings in the polyethylene rim of the RM press-fit socket.

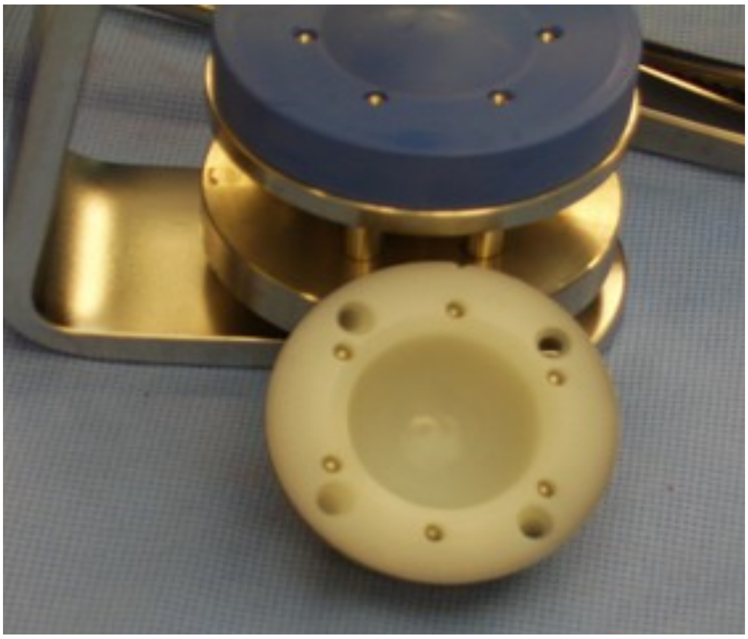

Figure 3 Pelvic radiograph showing the tantalum acetabular and socket markers after implantation of the cementless RM press-fit socket without any additional screw fixation.
Yellow arrows= fiducial cage markers
Green arrows= control cage markers
Red arrows= acetabular bone markers
Blue arrow = socket marker

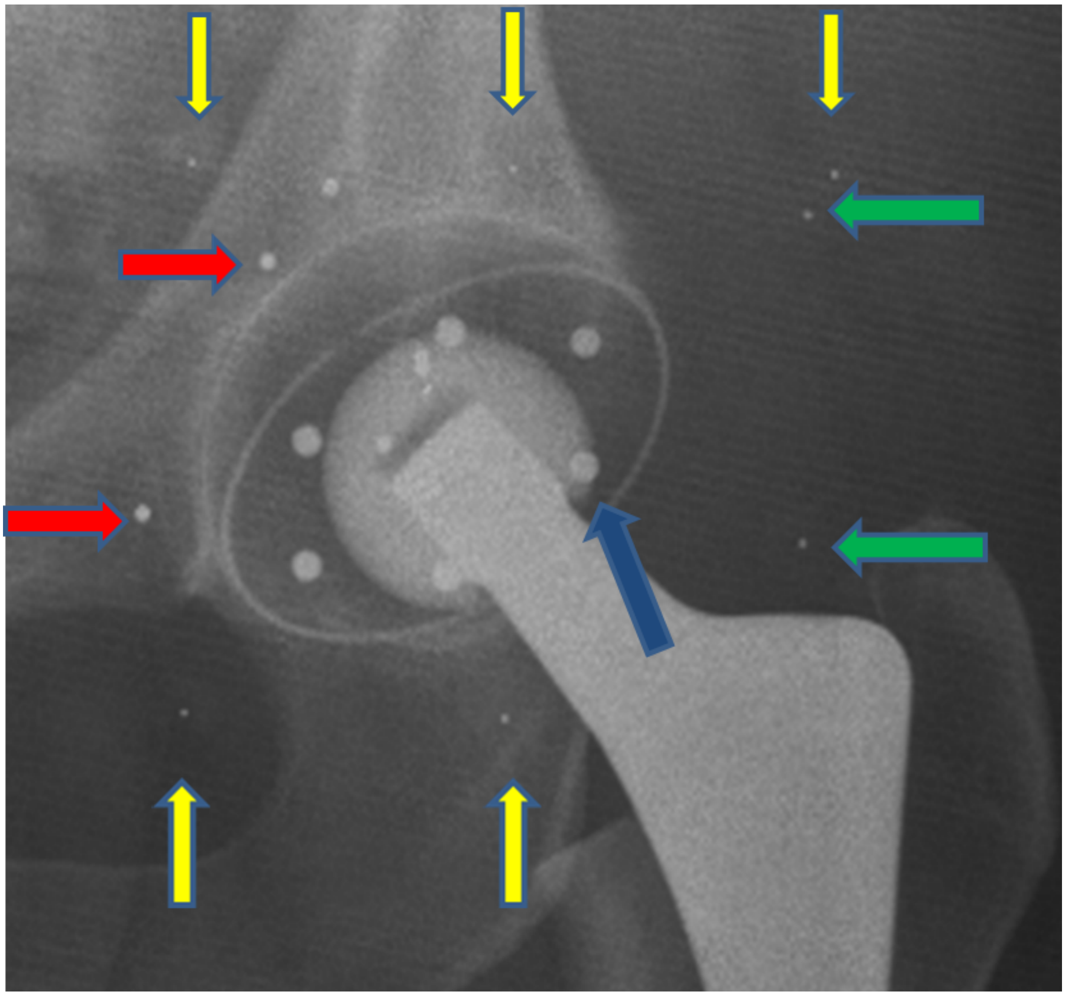

Figure 4 Study flow chart, CONSORT 2

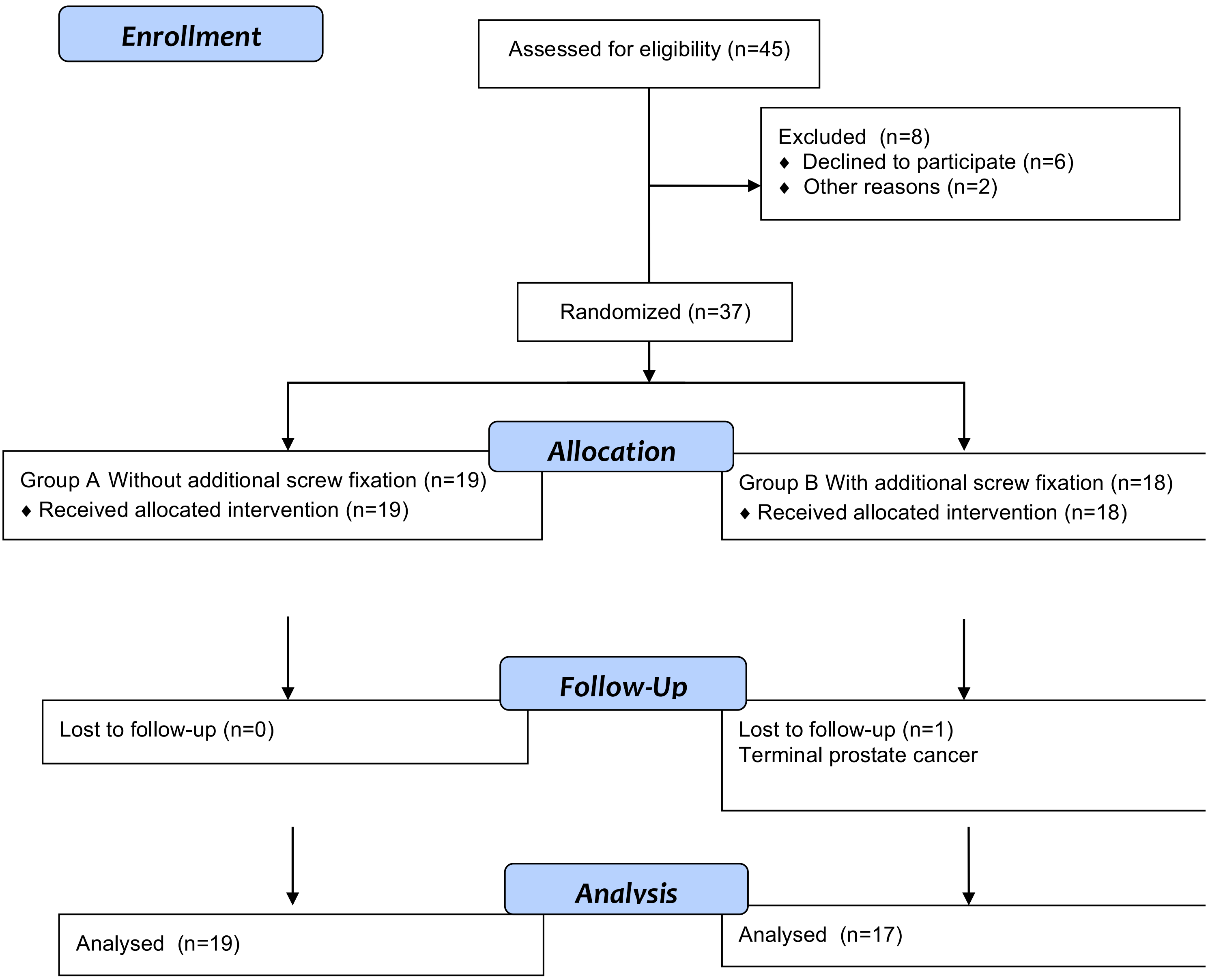

Figure 5 a, b, c, d, e, f Migration patterns (translation or rotation) of the sockets with and without additional screws.

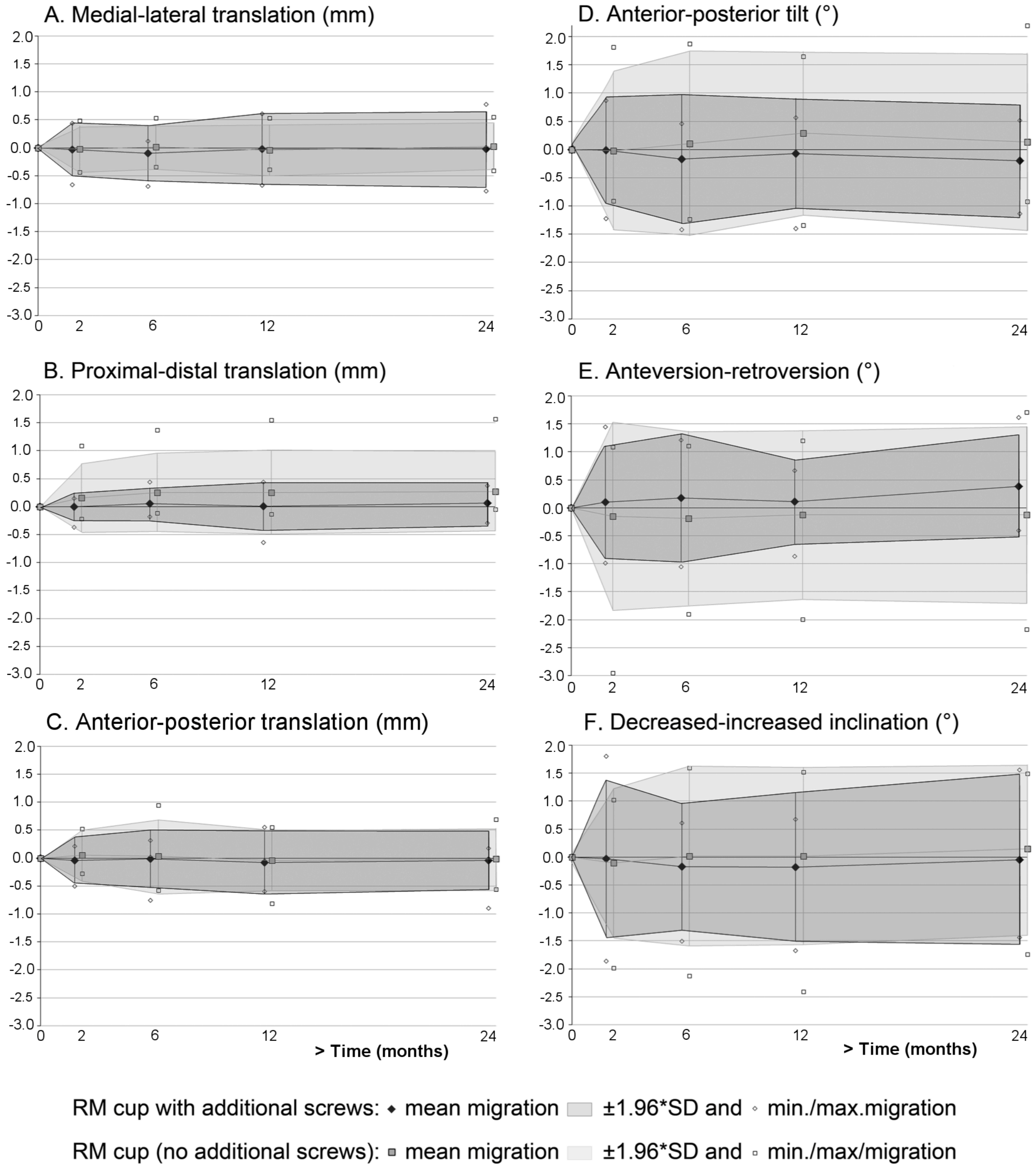

Table 1 The detection limits of the RSA method (precision), based on the analysis of double examinations at 2 months, calculated using the Bland-Altman method.

	Transverse Axis	Longitudinal axis	Sagittal axis
Translations (mm) (N=30)	0.18	0.16	0.36
Rotation (degree) N=29)	0.95	0.95	0.75

Table 2 Study demographics

	Group A without additional screw fixation	Group B with additional screw fixation
Number of patients	19	18
M/F	8/11	7/11
Age (mean, yr) (SD)	64 (8)	62 (6)
BMI (mean, Kg) (SD)	25 (3)	26 (2)
Operation Time (minutes)	71 ± 11	71 ± 12

Table 3 RSA measurements: Translations and rotations at the 2-year follow-up; Mean (95%CI)

	Group A without additional screw fixation	Group B with additional screw fixation
Translations (mm)		
Medial-Lateral	0.03 (-0.36 to 0.42)	-0.02 (-0.69 to 0.65)
Proximal-Distal	0.27 (-0.44 to 0.98)	0.06 (-0.31 to 0.43)
Anterior-Posterior	-0.02 (-0.57 to 0.53)	-0.05 (-0.56 to 0.46)
Rotations (°)		
Transverse axis	0.13 (-1.44 to 1.7)	-0.20 (-1.18 to 0.78)
Longitudinal axis	-0.13 (-1.72 to 1.46)	0.39 (-0.51 to 1.29)
Sagittal axis	0.15 (-1.36 to 1.66)	-0.05 (-1.56 to 1.46)

Table 4 Clinical scores (Harris Hip Score and Oxford Hip Questionaire);Median (Range)

	Group A Without additional screw fixation	Group B With additional screw fixation
HHS pre operative	61 (39-79)	52 (41-85)
HHS 2-year FU	100 (81-100)	97 (74-100)
Oxford pre operative	38 (30-47)	37 (27-54)
Oxford 2-year FU	16 (14-48)	15 (14-36)


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Chapter 6:

Periacetabular bone mineral density changes after resurfacing hip arthroplasty versus conventional total hip arthroplasty. A randomized controlled DEXA study.

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Abstract:

Introduction:
A randomized controlled trial was performed to evaluate acetabular bone mineral density (BMD) changes after hip resurfacing (RHA) versus an established conventional total hip arthroplasty (THA).
Methods:
A total of 71 patients were allocated randomly to receive either an RHA press-fit cobalt-chromium cup (n=38) or a THA with a threaded titanium cup and polyethylene-metal-inlay insert (n=33). The BMD in five separate periacetabular regions of interest (ROI) was prospectively quantified preoperative until 24 months.
Results:
We found relative stable BMD values in the acetabular bone surrounding a RHA and a general decrease in BMD surrounding THA during follow-up.
Conclusion:
In contrast to our hypothesis, periacetabular BMD was better preserved after RHA than after placement of a conventional THA. Long-term follow-up studies are necessary to see whether this benefit in bone preservation sustains over longer time periods and whether it is turned into clinical benefits at future revision surgery.

Introduction:

One of the biggest concerns in total hip arthroplasty is long-term acetabular fixation and preservation of bone stock. According to the Swedish hip register 65% of all re-operations are because of an acetabular component revision. [Malchau, 1993] A 30-year follow-up of the Charnley arthroplasty by Callaghan et al. [Callaghan 2004] shows that revision of the cup is three times more common than stem revision. Polyethylene wear of acetabular components is a key factor in the development of periprosthetic osteolysis. [Harris 2001, Dumbleton 2002] Periprosthetic osteolysis with loosening of the socket frequently opposes the orthopedic surgeon with challenging acetabular bone defect reconstructions. Metal-on-metal (MoM) hip arthroplasty was introduced as an alternative to overcome polyethylene wear related prosthetic failure. Proposed advantages are a reduction of wear, a subsequent lower incidence of periprosthetic osteolysis and eventually improved prosthetic survival. [Dumbleton 2005] On the other hand, a resurfacing hip prosthesis needs a rigid and thick shell press-fit socket. Such a relatively thick and rigid socket makes the implant stiffer and more susceptible to localized bone resorption caused by stress shielding behind the implant. [Digas 2004] These press-fit cups transmit forces sideways to the peripheral cortical bone, which induces stress-shielding and a subsequent decrease of the cancellous bone mineral density (BMD) behind the cup. [Wright 2001, Morscher 1997, Mueller 2006] The main theoretical benefit of resurfacing is the bone-preserving nature of the technique on the femoral side, however, when stress shielding results in osteolysis behind the cup, this benefit would be ineffective, if not detrimental. Finite element analyses predict medial bone loss up to 50% caused by stress shielding, and a bone gain near the prosthetic rim of press-fit cups (which is the main loading site of the pelvis). [Levenston 1993] Clinical DEXA studies on metal-on-poly (MoP) conventional THA confirm these results. [Kim 2007, Laursen 2007] Little is known about periprosthetic acetabular BMD changes around MoM implants and resurfacing hip arthroplasty (RHA) in particular. So far, only one study evaluated the acetabular BMD after RHA. [Yahia 2011] In that study the periacetabular BMD was evaluated 1 year after an RHA and compared to the BMD in the contralateral non-operated hip, no prospective changes in BMD were recorded in this study. A randomized comparison between RHA and conventional THA for periacetabular BMD changes has not been previously reported. For this reason, we performed a prospective randomized controlled trial of an RHA versus a conventional MoM THA and evaluated BMD changes in five periprosthetic regions of interest (ROI) of the acetabulum. We hypothesized that due to stress shielding behind the RHA cup a more profound BMD decrease would be encountered as compared to an established threaded conventional THA cup.

Methods:

This randomized study was designed to compare, amongst other outcome parameters, the periprosthetic BMD changes in the acetabulum of patients who received an RHA against a conventional uncemented MoM THA. The BMD of the femoral side of these patients has already been reported by our group, [Smolders 2010] we now present a further recruitment of patients.
From June 2007 till January 2010 82 patients were randomly assigned to receive one of the two hip implants types (RHA versus THA). A computer-generated variable block schedule was used for randomization. The randomization list was generated by an independent statistician and the resulting treatment allocations were stored in sealed opaque envelopes. Randomization occurred at the outpatient consultation by the orthopedic surgeon at the time of planning the hip arthroplasty. Patient and the surgeon could not be blinded for the eventual type of implant, neither could they influence the randomization outcome. The criteria for inclusion were patients under 65 years, who needed a primary hip replacement for osteoarthritis. Patients were excluded if they had (previous) infection of the hip or other sites, hip fracture, avascular necrosis with collapse, osteoporosis, neoplasm, or renal failure. Inclusion and subsequent follow-up of patients is summarized in the consort statement (Figure 1).

Five patients (three RHA, two THA) were lost to follow-up; directly after operation (n=2), after 12 months (n=1) and after 24 months (n=2). Three patients (one RHA, two THA) did not participate in all follow-up moments because of revision after 24 months, one patient passed away. One RHA was revised for unexplained pain and subtle signs of a periprosthetic adverse reaction to metal debris (ARMD) on MRI scan, in two patients with a THA a relatively simple insert exchange was performed for recurrent dislocation. Seventy-one patients had a follow-up of 12 months; 38 RHA patients, and 33 THA patients, 51 patients had a follow-up of 24 months (Table 3). There were no significant differences between both groups for age, gender and BMI (Table 1). Approval from the regional ethics committee from the Radboud University Nijmegen Medical Centre was obtained (LTC 419- 071206). All patients agreed to sign an informed consent form. The study was performed in compliance with the Helsinki declaration, and is registered in EudraCT (2006-005610-12).

Surgical technique

Preoperative digital templating (Easyvision, Philips Medical Systems, Eindhoven, The Netherlands) for positioning of the implant was carried out for all patients. All surgeries were carried out by one of the authors (JvS) and two other experienced hip surgeons through a posterolateral approach. In the RHA group a resurfacing prosthesis was implanted with both components made of a cast, heat-treated solution-annealed Co–Cr alloy (Conserve plus; Wright Medical Technology, Arlington, Tennessee, USA) (Figure 2). The femoral component was cemented with low-viscosity cement after preparation of the femoral head with multiple subchondral anchor holes, the 6-mm hydroxyapatite (HA)-coated acetabular component was pressfitted in the acetabulum (underreamed by 1 mm). The surgical technique has been described earlier. [Amstutz 2006] In the THA group, an uncemented grit-blasted titanium alloy Zweymüller tapered stem was press-fitted in the femoral canal and a threaded solid backed titanium acetabular component was screwed in the acetabulum without additional screw fixation (Figure 3).

As this trial was designed to minimize confounding variables, a metal-on-metal bearing was also used for the THA together with a metal 28-mm head (Alloclasic Zweymüller CSF with Metasul inlay; Zimmer Orthopaedics, Warsaw, Indiana, USA). Both groups received identical antibiotic prophylaxis with Cephalosporin preoperative and 24 h postoperative, 3 days of Diclophenac for periarticular ossification prophylaxis, and thrombosis prophylaxis with Fraxiparine until 6 weeks postoperative. Patients were rehabilitated with immediate unrestricted weight bearing according to patient's tolerance. [Hol 2010]

Bone densitometry

BMD measurements and software have been described previously by our group. [Smolders 2010] Briefly, the BMD was measured by dual energy xray absorptiometry (DEXA) (Lunar Prodigy, GE Healthcare, United Kingdom) with software package 13.60.033. Measurements were performed 2 weeks preoperatively and then at 3, 6, 12 and 24 months after surgery. The patients were positioned supine with their feet attached to a positioning device to obtain a standardized reproducible 20° of internal rotation. Mortimer et al. [Mortimer 1996] found that a range of 15° internal to 15° external rotation yields a precision of 1.7%. Five ROI were carefully defined, modified from the regions defined by Wilkinson et al. [Wilkinson 2001] (Figure 4).

For each patient standardized analysis of each ROI was obtained using the manufacture's metal exclusion software. Since the ROI could only be defined after implantation of the hip arthroplasty, these ROIs were imported in the preoperatively available DEXA scan to measure baseline BMD levels in the absence of the implant. Tests using phantoms have shown that DEXA is accurate for the determination of periprosthetic BMD with an error below 1%. [Kiratli 1992] In addition, precision and reproducibility of the DEXA measurements for each region in this study were assessed on 15 patients (11 male, 4 female; 8 RHA and 7 THA) with a mean age of 53 years (range 34–63). They underwent two sequential DEXA examinations of the involved hip, taken on the same day and measured twice by two independent laboratory assistants, with repositioning between each scan. The precision error was expressed as the coefficient of variation percentage, calculated according to Aldinger et al. [Aldinger 2003] The precision in our study (Table 2) was adequate and consistent with the literature. [Wilkinson 2001, Aldinger 2003, Albanese 2009] Additional quality controls for the DEXA equipment were undertaken daily according to the manufacturer's guidelines to verify the stability of the system. No change was observed during the entire study period.

Statistical analysis

We conducted a power analysis based on the article of Lian et al.{Lian, 2007} The minimal number of participants needed in each group, to obtain a power of 80%,was determined at 34 patients,with a calculated difference of 2.98 percent (SD 6.14) in mean relative BMD. All BMD data were normally distributed and the differences in each ROI between the two groups preoperatively and at 3, 6, 12 and 24 months after surgery were analyzed using a Student's t-test. The change of the BMD in each ROI over each observation period was assessed by repeated analysis of variance for the two groups. To compare the changes between the time intervals, the mean relative BMD as a percentage of the baseline value (presented as 100%) was calculated. All normally distributed data are expressed as group means±SD. When not normally distributed a median and a range are given. Differences were considered statistically significant at $p<0.05$ All statistical analyses were performed using SPSS software (version 18.0).

Results:

Patient characteristics are presented in Table 1. The mean operating time for the RHA group was significantly longer than for the THA group ($p<0.001$), demonstrating the inherent technical difficulty of the resurfacing procedure. The acetabular cup of the THA was significantly bigger than the RHA ($p<0.001$).
Preoperatively the BMD of ROI 3 (caudal zone) significantly differed between the two study groups with a higher BMD in the RHA group ($p=0.006$) (Table 3).
The mean relative BMD change for each ROI, obtained during the 24-month follow-up, is shown in Figure 5.
For RHA patients, the mean relative BMD of the medial ROIs 2 and 4 showed a significant overall decrease ($p<0.001$, $p=0.022$) in time. Cranial and caudal ROIs 1, 3 and 5 remained stable around the preoperative baseline levels values until 24 months ($p=0.356$, $p=0.404$, and $p=0.274$ respectively) (Figure 5). After a THA the BMD of ROIs 1, 2, 3 and 4 showed a significant decrease ($p=0.001$, $p<0.001$, $p<0.001$, and $p=0.043$ respectively). This decrease was most significant at 3 months ($p=0.004$, $p<0.001$, $p=0.006$, and $p=0.023$ respectively). The mean relative BMD of ROI 5 remained stable for THA patients ($p=0.055$).

There were significant differences between the two groups in mean relative BMD. Twelve months after surgery the mean relative BMD was significantly higher for RHA in all ROIs except for ROI 4 ($p=0.028$, $p=0.001$, $p=0.040$, $p=0.293$, and $p=0.006$, for ROIs 1, 2, 3, 4 and 5 respectively). At 24 months a significantly higher mean relative BMD still existed for ROIs 1, 2 and 5 ($p=0.030$, $p=0.046$, $p=0.013$). In ROIs 1 and 2 there was also a difference at 6 months in favor of RHA ($p=0.017$, $p=0.018$). The pattern of postoperative BMD decrease in ROI 2 was similar in both groups (Figure 5) with a steep decline in BMD from baseline till the first evaluation at 3 months.
A difference of 13.6% between the two groups in mean relative BMD was obtained for the caudal ROI 3, at 12 months. In this region the BMD increased up to 105% for RHA versus a decrease up to 91% for THA ($p=0.040$). At 24 months there were only significant differences between RHA and THA in ROI s1, 2 and 5; 7.9% ($p=0.030$), 10.4% ($p=0.046$) and 8.1% ($p=0.013$) respectively, in favor of RHA.

Discussion:

This prospective randomized controlled study shows that after an RHA both cranial ROIs remained stable around baseline levels whereas for one cranial ROI the BMD decreased significantly after THA. As for the two medial ROIs, the BMD decreased significantly for both implants ($p<0.05$), in one of these ROIs this difference was in favor of the RHA group. BMD remained stable in the caudal ROI for RHA, whereas a significant decrease was found in the caudal ROI for THA.

These results suggest that, unlike our hypothesis, the acetabular bone was better preserved after the RHA with the rigid press-fit cup. The observed decrease in BMD medial to the cup (ROIs 2 and 4) of 23% and 8.5% for RHA and 32% and 3% for THA at 24 months are in concordance with earlier literature on BMD changes after press-fitted cups of a conventional THA. In clinical [Laursen 2007, Digas 2006, Stepniewski 2008] and finite element [Levenston 1993, Huiskes 1987] studies a 5% to 50% decrease was found in the ROI medial to the acetabular cup. The BMD preservation of RHA patients was most profound cranial to the cup (ROIs 1 and 5) for RHA patients. This is in accordance with the recent report from Yahia et al. [Yahia 2011] where similar results were found 2 years postoperative. In contrast to other studies, where a 3% to 35% decrease of cranial acetabular BMD was seen after the placement of a press-fit cup, [Wright 2001, Mueller 2006, Digas 2006, Pitto 2008, Baad-Hansen 2011], we only found a significant decrease for one of the two cranial ROIs in the THA group. As confirmed in other studies we found the most rapid changes in BMD in the first 6 months after surgery, but (smaller) BMD changes still occurred until 24 months. [Baad-Hansen 2011, Kröger 1998, Venesmaa 2003]

Wear and osteolysis are probably the most important factors that limit the survival of metal-on-poly THA. The articulation of the metal ball against the polyethylene cup of the acetabular component creates polyethylene wear debris. The macrophage-mediated response to these implant-derived particulate debris and probably other stimuli, results in local osteoclastic bone resorption. [Archibeck 2001] Using a metal-onmetal bearing might prevent this wear-induced osteolysis, but does not overcome stress shielding and subsequent adaptive remodeling. Stress shielding is a major reason for periprosthetic bone loss after THA, because of changes in load distribution as a consequence of the rigidity of an implant. [Wright 2001, Huiskes 1987] Theoretically, the thicker and stiffer press-fit acetabular cup of an RHA may increase periacetabular bone stress shielding. [Wright 2001, Morscher1997, Mueller 2006, Yahia 2011, Venesmaa 2003] The rationale behind differences in stress shielding for press-fit or threaded cups is based on the elasticity modulus, whereas titanium is half as stiff as cobalt–chromium–molybdenum alloy (modulus of elasticity 114 vs. 214 GPa). Therefore, one would expect that the stiffer and more robust monoblock cobalt– chromium shell would show more bone loss because of increased stress shielding as shown “in vitro”. [Wright 2001] We found the opposite; the monoblock shell preserved relatively more cranial acetabular bone compared to the titanium threaded cup. Possibly the differences in modulus of elasticity between the two bearings in vivo were insufficient to effect the same quantitative changes in the BMD over the 2 years of the study.

In our observations that overall more BMD decline was encountered for THA patients as compared to RHA, we also have to realize that firm conclusions can only be drawn for the implants used in our study. The use of a metal-on-metal bearing with the THA may for example have stiffened the acetabular component leading to more profound stress shielding and BMD decline. On the other hand we do feel that this potential influence may have been minimal. What we know from our clinical data of these patients is that RHA patients reach higher activity levels then patients with a conventional THA, [Smolders 2011] this might be a possible confounder. This higher postoperative activity level may have contributed to a reduced postoperative bone loss in the RHA group. [Rosenbaum 2006] On the other hand the encountered difference in activity score in favor of RHA patients was only limited and we do not feel that the difference in BMD changes from can be explained by this phenomenon.
A remarkable finding in our study is the major decrease of BMD within the first 3 months of ROI 2 in both groups, whereas in other clinical studies [Digas 2006, Kim 2007] a more gradual medial BMD loss between 5% and 17% until 1-year postoperative has been described. All these studies, however, have their baseline measurements 1 to 6 weeks postoperative and therefore all measurements on BMD were performed on the postoperative situation with the implant in situ. One of the strengths of our study was the use of serial BMD measurements which are recorded truly against the preoperative baseline values, unlike the study of Yahia et al. [Yahia 2011, Kim 2007] who compared with the contralateral non-operated side only at one time interval. We believe that the steep decline in BMD in the medio-cranial ROI 2 between the preoperative situation and 3 months after surgery can simply be explained iatrogenic by subchondral reaming and bone removal at the time of implantation and not by stress shielding. There are some remarkable findings in ROI 3 as well. At first, we found a lower preoperative BMD for the THA patients. We do not have an explanation for this difference, as all other patiënt characteristics appeared to be matched after randomization. It could have had an influence on the results, as there is a significant relationship between periprosthetic femoral bone loss and the preoperative BMD. [Kröger 1998] Secondly, at 12 months we found an increase in BMD to 105% for RHA, an outlier of 260% can explain this Without this outlier the mean relative BMD would be 100%. Lastly, at all time intervals the standard deviation in ROI 3 of the RHA groups is almost twice as large compared to THA. The reason might be the difficulty of ROI analysis, although the coefficient of variation is only 3%, which is relatively low.

Limitations of this study consist of the fact that patients and reviewing surgeons were not blinded. However, we do not see how these two factors can be overcome and are convinced that this has not biased our results. In RHA patients the cup size used appeared to be significantly larger than for THA patients. This can be explained by the fact that the acetabular preparation was different between the RHA and THA socket. In the THA group a threaded conical cup was screwed in the acetabular socket, which mandated removal of a relatively large amount of subchondral acetabular bone. This difference in acetabular preparation and cup size between groups is a confounding factor that theoretically may have affected the subsequently observed change in periprosthetic BMD for both implants, however, we feel that since our change in BMD is recorded against preoperative baseline levels this influence can only be very limited. In addition the software used to calculate the actual change in BMD did correct for the iatrogenic bone removal and thus a potential influence from this phenomenon on our results was also avoided.

Another limitation is the presentation of the results up to 2 years, whereas stress shielding is a process of years. Therefore we will continue to follow these patients in time, as these data are part of a larger randomized trial on this matter. On the other hand, we know from the literature that a decrease in BMD after various types of arthroplasty mainly occurs during the first 2 years. [Kröger 1998, Venesmaa 2003] Additionally, although DEXA remains a safe and reliable method to evaluate changes in BMD, [Kiratli 1992] the method only measures BMD and does not discriminate cancellous from cortical bone, and it is a twodimensional projection instead of a three-dimensional measurement which can be performed with computed tomography.
Protection of bone stock after hip arthroplasty is important, especially for the relatively young population, since revision surgery is likely to occur. In this study we focused on periprosthetic BMD changes in the acetabulum after a bone-preserving RHA and the potential pitfall of gradual bone resorption due the effects of an acetabular cup implantation. We found that after placement of a thick press-fit resurfacing cup the supposed decrease of BMD seems not to be as critical as indicated in some finite element studies. [Levenston 1993] We can conclude that, on the short term, an RHA press-fit cup does not lead to a more decline in periprosthetic BMD compared to an established conventional threaded titanium acetabular component. The RHA used in this study thus appears to be relatively bone preserving, also on the acetabular side, however stress shielding is a process of years and this follow-up so far is limited to 24 months. RHA therefore does not appear to be more susceptible for periprosthetic acetabular bone loss from stress shielding as compared to an established titaniumthreaded shell with a well-defined clinical track record. Similar findings were already recorded by us for the femoral side [Smolders 2010] and thus we believe that it is safe to conclude that RHA is indeed bone preserving on both the acetabular and the femoral sides. However, as these results are different from our hypothesis, clinical and biomechanical studies are necessary to assess why bone preservation is better around the RHA compared to the conventional THA. A better understanding of periprosthetic bone remodeling may lead to further improvements of hip replacement implants.

Literature:

1. Malchau H, Herberts P, Ahnfelt L. Prognosis of total hip replacement in Sweden: Follow-up of 92,675 operations performed 1978–1990. Acta Orthop. 1993;64:497-506.
2. Callaghan JJ, Templeton JE, Liu SS, et al. Results of charnley total hip arthroplasty at a minimum of thirty years. A concise follow-up of a previous report. J Bone Joint Surg. 2004;86:690-5.
3. Harris WH. Wear and periprosthetic osteolysis: The problem. Clin Orthop Relat Res. 2001;393:66-70.
4. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty. 2002;17:649-61.
5. Dumbleton JH, Manley MT. Metal-on-metal total hip replacement: What does the literature say? J Arthroplasty. 2005;20(2):174-88.
6. Digas G, Thanner J, Anderberg C, et al. Bioactive cement or ceramic/porous coating vs. Conventional cement to obtain early stability of the acetabular cup randomised study of 96 hips followed with radiostereometry. J Orthop Res. 2004;22:1035-43.
7. Wright JM, Pellicci PM, Salvati EA, et al. Bone density adjacent to press-fit acetabular components: A prospective analysis with quantitative computed tomography. J Bone Joint Surg. 2001;83:529-36.
8. Morscher E, Berli B, Jockers W, et al. Rationale of a flexible press fit cup in total hip replacement. 5 year followup in 280 procedures. Clin Orthop Relat Res. 1997;341:42-50.
9. Mueller LA, Kress A, Nowak T, et al. Periacetabular bone changes after uncemented total hip arthroplasty evaluated by quantitative computed tomography. Acta Orthop. 2006;77(3):380-5.
10. Levenston ME, Beaupré GS, Schurman DJ, et al. Computer simulations of stress-related bone remodeling around noncemented acetabular components. J Arthroplasty. 1993;8:595-605.
11. Kim Y-H, Yoon S-H, Kim J-S. Changes in the bone mineral density in the acetabulum and proximal femur after cementless total hip replacement: Alumina-on-alumina versus alumina-on-polyethylene articulation. J Bone Joint Surg. 2007;89:174-9.
12. Laursen M, Nielsen P, Søballe K. Bone remodelling around ha-coated acetabular cups. Int Orthop. 2007;31:199-204.
13. Yahia C, Diwanji S, Ganapathi M, et al. Supra acetabular bone mineral density measurements after hip resurfacing arthroplasty at short term follow up. Hip Int. 2011;21:468-74.
14. Smolders JMH, Hol A, Rijnders T, et al. Changes in bone mineral density in the proximal femur after hip resurfacing and uncemented total hip replacement: A prospective randomized controlled study. J Bone Joint Surg. 2010;92:1509-14.
15. Amstutz HC, Beaule PE, Dorey FJ, et al. Metal-on-metal hybrid surface arthroplasty. Surgical technique. J Bone Joint Surg. 2006;88(1_suppl_2):234-49.
16. Hol A, van Grinsven S, Lucas C, et al. Partial versus unrestricted weight bearing after an uncemented femoral stem in total hip arthroplasty: Recommendation of a concise rehabilitation protocol from a systematic review of the literature. Arch Orthop Trauma Surg. 2010;130:547-55.
17. Mortimer ES, Rosenthall L, Paterson I, et al. Effect of rotation on periprosthetic bone mineral measurements in a hip phantom. Clin Orthop Relat Res. 1996;324:269-74.

18. Wilkinson J, Peel N, Elson R, et al. Measuring bone mineral density of the pelvis and proximal femur after total hip arthroplasty. J Bone Joint Surg. 2001;83:283-8.
19. Kiratli BJ, Heiner JP, MvBeath AA, et al. Determination of bone mineral density by dual x-ray absorptiomatry in patrients with uncemented total hip arthorplasty. J Orthop Res. 1992;10:836-44.
20. Aldinger PR, Sabo D, Pritsch M, et al. Pattern of periprosthetic bone remodeling around stable uncemented tapered hip stems: A prospective 84-month follow-up study and a median 156-month cross-sectional study with dxa. Calcif Tissue Int. 2003;73:115-21.
21. Albanese CV, Santori FS, Pavan L, et al. Periprosthetic dxa after total hip arthroplasty with short vs. Ultra-short custom-made femoral stems. Acta Orthop. 2009;80:291-7.
22. Lian Y, Pei F, Yoo M, et al. Changes of the bone mineral density in proximal femur following total hip resurfacing arthroplasty in osteonecrosis of femoral head. J Orthop Res. 2007;26:453-9.
23. Digas G, Kärrholm J, Thanner J. Different loss of bmd using uncemented press-fit and whole polyethylene cups fixed with cement: Repeated dxa studies in 96 hips randomized to 3 types of fixation. Acta Orthop. 2006;77:218-26.
24. Stepniewski AS, Egawa H, Sychterz-Terefenko C, et al. Periacetabular bone density after total hip arthroplasty: A postmortem analysis. J Arthroplasty. 2008;23:593-9.
25. Huiskes R. Finite element analysis of acetabular reconstruction: Noncemented threaded cups. Acta Orthop. 1987;58:620-5.
26. Pitto R, Bhargava A, Pandit S, et al. Retroacetabular stress-shielding in tha. Clin Orthop Relat Res. 2008;466:353-8.
27. Baad-Hansen T, Kold S, Nielsen PT, et al. Comparison of trabecular metal cups and titanium fiber-mesh cups in primary hip arthroplasty. Acta Orthop. 2011;82:155-60.
28. Kröger HPJ, Venesmaa P, Jurvelin J, et al. Bone density at the proximal femur after total hip arthroplasty. Clin Orthop Relat Res. 1998;352:66-74.
29. Venesmaa PK, Kroger HP, Jurvelin JS, et al. Periprosthetic bone loss after cemented total hip arthroplasty: A prospective 5-year dual energy radiographic absorptiometry study of 15 patients. Acta Orthop Scand. 2003;74:31-6.
30. Archibeck M, Jacobs J, Roebuck KA, et al. The basic science of periprosthetic osteolysis. Instr Course Lect. 2001;50:185-95.
31. Smolders JM, Hol A, Rijnberg WJ, et al. Metal ion levels and functional results after either resurfacing hip arthroplasty or conventional metal-on-metal hip arthroplasty. Acta Orthop. 2011;82:559-66.
32. Rosenbaum TG, Bloebaum RD, Ashrafi SB, et al. Ambulatory activities maintain cortical bone after total hip arthroplasty. Clin Orthop Relat Res. 2006;450:129-37.
33. Kim YH, Yoon SH, Kim JS. Changes in the bone mineral density in the acetabulum and proximal femur after cementless total hip replacement: Alumina-on-alumina versus alumina-on-polyethylene articulation. J Bone Joint Surg. 2007;89:174-9.

Figure 1 Consort statement: Flow chart of participants throughout the study.

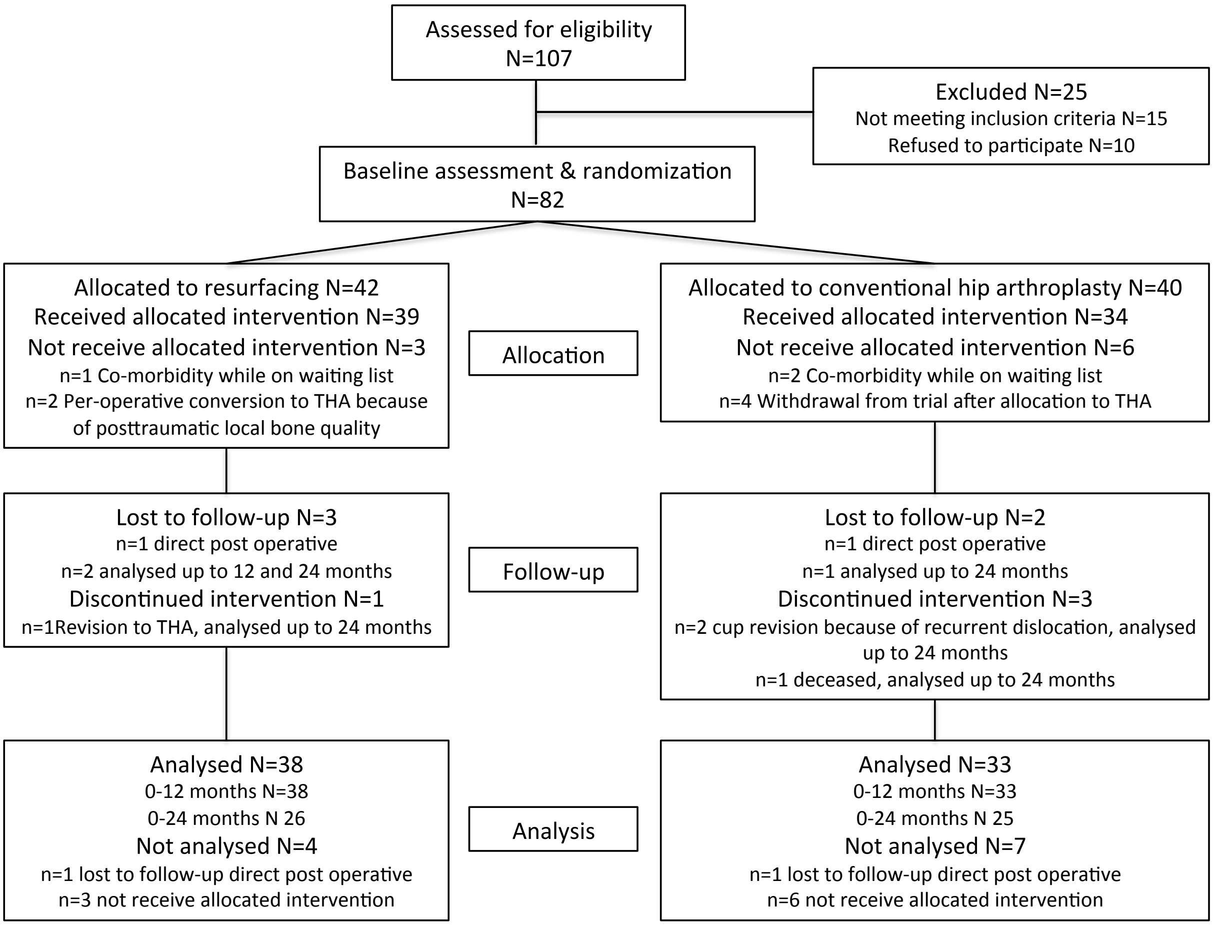

Figure 2 Conserve plus® hip resurfacing; Wright Medical Technology, Arlington, Tennessee, USA**.**

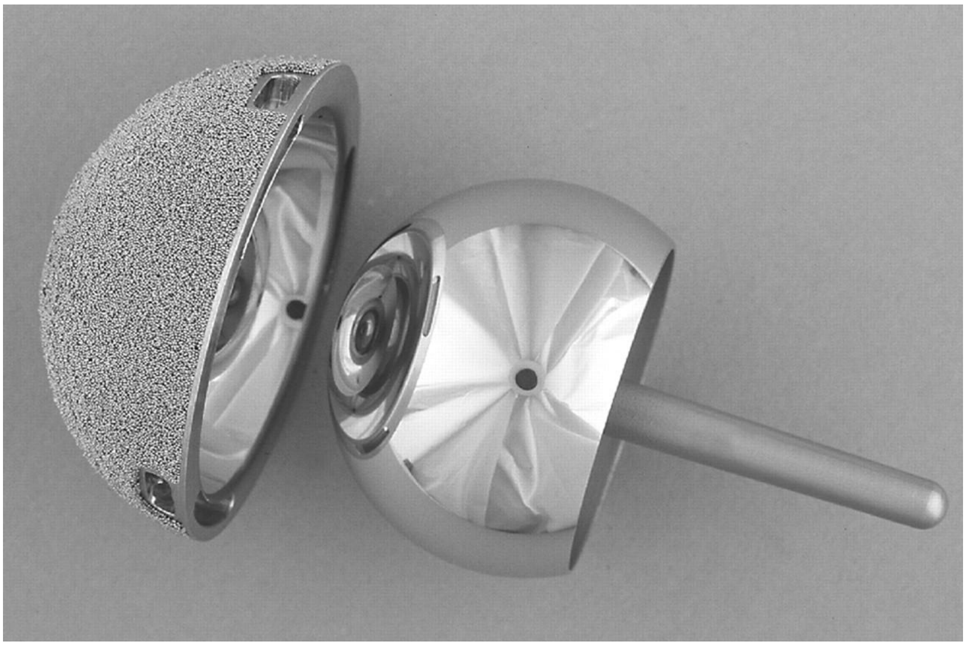

Figure 3 Alloclassic® Zweymüller® CSF with Metasul® inlay; Zimmer Orthopaedics, Warsaw, Indiana, USA

Figure 4 a and b Typical example of the measurement of BMD in the separate ROIs by dual energy X-ray absorptiometry of RHA (A) and THA (B).

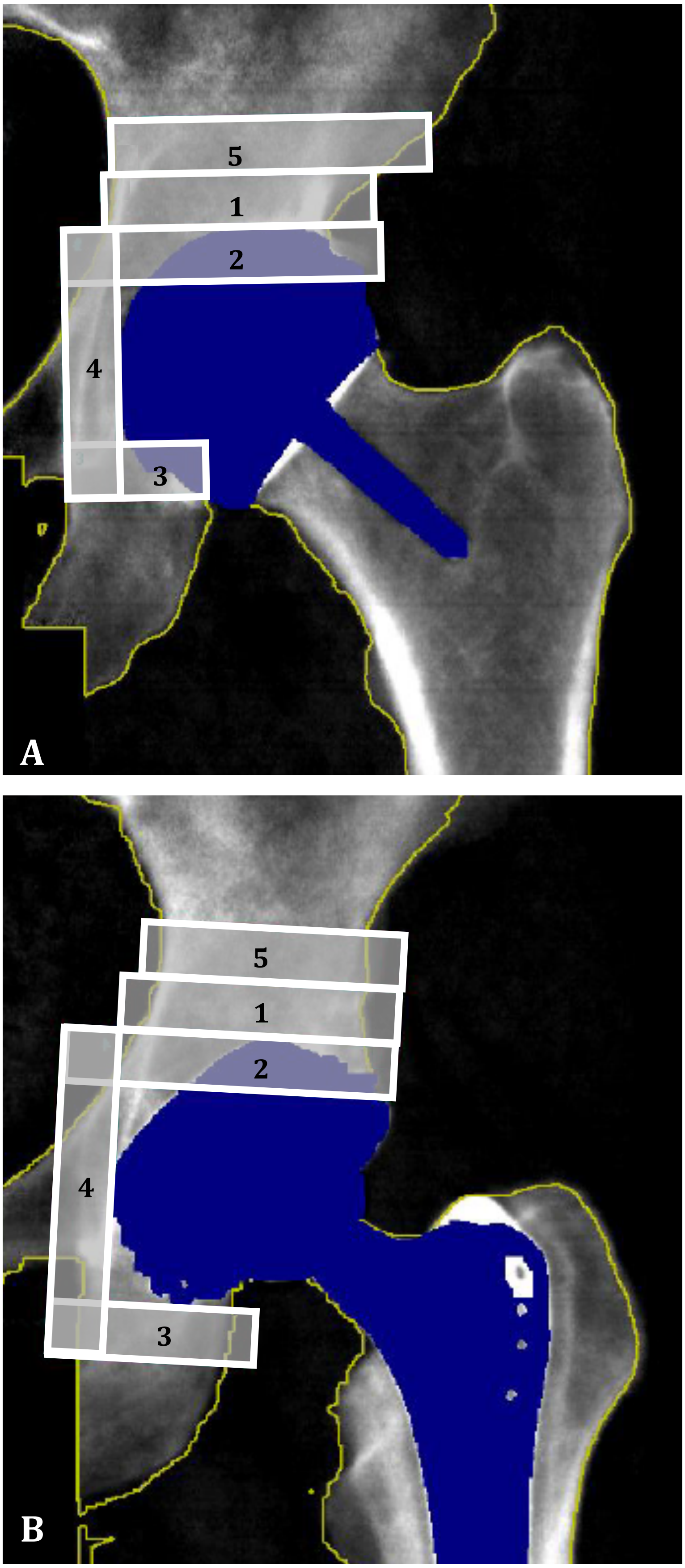

Figure 5 Graph of the mean relative BMD change, as percentage of preoperative baseline values with error bars indicating one standard deviation for all ROI of RHA (black line) versus THA (gray line). Cranial to the acetabular cup ROI 1, Medial to the acetabular cup ROI 2, Caudal to the acetabular cup ROI 3, Medial to the acetabular cup ROI 4, Cranial to the acetabular cup ROI 5.

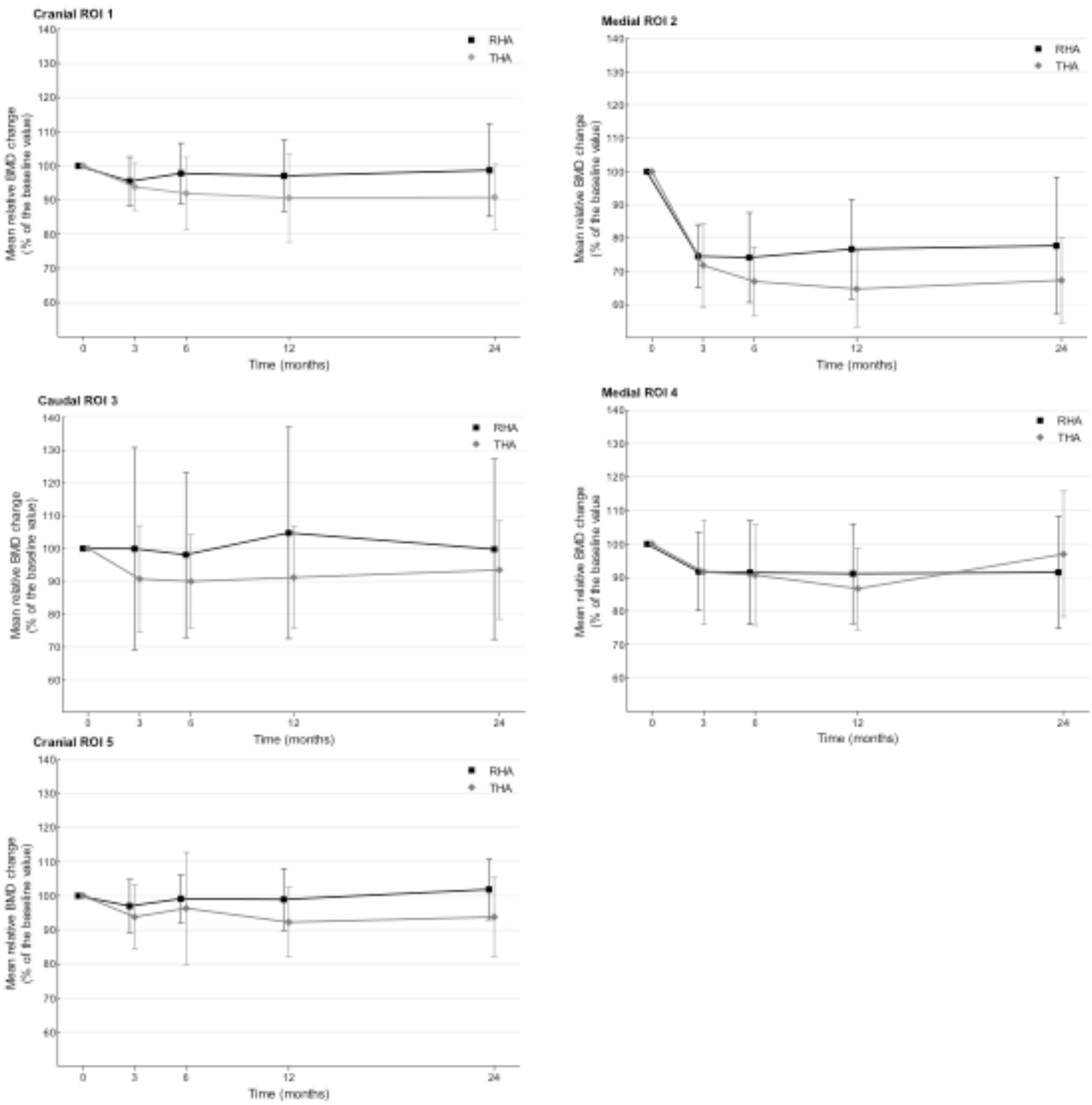

Table 1 Clinical details of the patients in both groups.

	RHA (N=38)	THA (N=33)	P
Gender (women/men)	17/21	13/21	0.637[a]
Mean BMI (SD)	26.1 (3.1)	28.0 (5.1)	0.083[b]
Median acetabular cup size (range)	54 (48-60)	64 (58-68)	<0.001[c]
Median age at operation in years (range)	57.5 (40.7)	59.1 (27.8)	0.475[c]
Diagnosis (OA/AVN/CHD)	35/1/2	32/0/2	0.639[d]
Median blood loss in mL (range)	300 (100-600)	250 (100-900)	0.993[c]
Mean operating time in minutes (range)	75.0 (40)	54.0 (45)	<0.001[b]

OA= Osteoarthritis, AVN= Vascular necrosis, CHD= Congenital hip dysplasia.
[a] Fisher's exact probability test, [b] Student's t-test, [c] Mann-Whitney U test, [d] Kruskall-Wallis test

Table 2 Percent coefficient of variation (CV%) in ROI to 5.

ROI	1	2	3	4	5	Mean (SD)
CV%	1.3	2.2	3.0	4.0	2.5	2.6 (0.9)

Table 3 Mean BMD (g/cm^2) (SD) for both groups in the postoperative period.

Group	Time	Cranial				Medial				Caudal	
	(months)	ROI 1		ROI 5		ROI 2		ROI 4		ROI 3	
RHA											
(n=35)	0	1.78	(0.24)	1.71	(0.31)	2.01	(0.29)	1.48	(0.48)	1.48[a]	(0.47)
(n=38)	3	1.73	(0.29)	1.70	(0.36)	1.54	(0.35)	1.39	(0.52)	1.48[a]	(0.47)
(n=38)	6	1.76	(0.30)	1.72	(0.34)	1.53[a]	(0.37)	1.39	(0.52)	1.45[a]	(0.45)
(n=38)	12	1.75	(0.33)	1.72	(0.36)	1.57[a]	(0.41)	1.39	(0.49)	1.53[a]	(0.51)
(n=26)	24	1.77	(0.41)	1.73	(0.37)	1.54[b]	(0.45)	1.40[b]	(0.54)	1.45[a]	(0.57)
THA											
(n=32)	0	1.78	(0.33)	1.76	(0.39)	2.03	(0.35)	1.34	(0.60)	1.19[a]	(0.35)
(n=33)	3	1.67	(0.29)	1.64	(0.35)	1.46	(0.29)	1.23	(0.56)	1.08[a]	(0.35)
(n=33)	6	1.63	(0.32)	1.67	(0.38)	1.35[a]	(0.28)	1.25	(0.54)	1.07[a]	(0.31)
(n=33)	12	1.61	(0.37)	1.61	(0.37)	1.31[a]	(0.27)	1.21	(0.57)	1.07[a]	(0.27)
(n=25)	24	1.60[b]	(0.35)	1.60[b]	(0.39)	1.34[b]	(0.29)	1.24[b]	(0.46)	1.05[a,b]	(0.24)

[a] Significant difference between RHA and THA ($p \leq 0.05$); [b] Significant difference against baseline at repeated measures within each ROI ($p \leq 0.05$)

Chapter 7:

Cancellous and cortical bone mineral density around an elastic press fit socket in hip arthroplasty.
A prospective 2 year follow up study using quantative CT BMD measurements.

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Submitted

Abstract:

Introduction:
The acetabular component has remained the weakest link in hip arthroplasty to achieve long-term survival. One of the potential explanatory factors for acetabular failure has been acetabular stress shielding. For this we investigated the effects of a cementless elastic socket on acetabular bone mineral density (BMD).
Methods:
During 2008-2009 we performed a single centre prospective cohort trial on 25 patients (mean age 64, SD 4, 18 females) in whom we implanted a cementless elastic press-fit socket. Using quantative BMD measurements on CT, we determined the change in BMD surrounding the acetabular component during a 2-year follow up period.
Results:
We found a significant decline of cancellous BMD (-14 to -35%) and a steady state of cortical BMD (4.8 to - 4.9%) surrounding the elastic press fit cup during the follow up period. The main decline was seen during the first 6 months after implantation. During the second year cancellous BMD showed a further decline in the medial and lower acetabular regions. Cortical BMD stabilized at two years.
Conclusion:
We found no evidence that an elastic press fit socket could prevent acetabular stress shielding during a two-year follow-up.

Introduction:

Sufficient bone stock is essential for reconstructive hip surgeons when performing revision hip surgery. On the femoral side of hip arthroplasty several authors have described a decline in bone stock due to femoral bone remodelling following the implantation of a femoral stem. [Engh 2003, Engh 1994] Femoral stress shielding has been accepted as a potential failure mechanism for which engineers have adapted the femoral stem design to prevent this phenomenon.

Although the acetabular component is deemed the weakest link in total hip arthroplasty, only a few authors have described, discussed and supported bone morphology changes after the implantation of an acetabular component. [Mueller 2007, Meneghini 2010, Pitto 2008 Schmidt 2002] In a native hip joint the stress transfer passes through the supero-medial acetabular bone, but finite element models have shown different load patterns after the implantation of cemented or cementless sockets. [Huiskes 1987, Levenston 1993]
Especially in cementless press-fit sockets, the main load transfer is at the peripheral rim of the acetabulum. This results in a unloading of the medial and supero-medial acetabular bone and a decline of bone density according to Wolf's law. [Wolf 1892] De unloading of bone and decline in bone density poses a risk for aseptic loosening. [Huo 2008] As a solution to this problem Levenston et al [1993] advocated the development of sockets with a more circumferential load transfer characteristics onto the acetabular bone. Meneghini et al [2010] showed that, when using an implant with a elastic modulus closer to human bone, better load transfer onto the surrounding bone occurs, resulting in less stress shielding and a higher quality of acetabular bone. In orthopaedics, polyethylene is a material with an elastic modulus approximating that of human bone. This feature of elastic modulus and the theory of optimal stress transfer onto the surrounding bone formed the basis of the development of the Robert Mathys (RM) cementless socket.

The purpose of our study was to evaluate the effect of press fit cementless sockets with low elastic modulus on the changes of acetabular bone mineral density using quantitative CT BMD (Bone Mineral Density) measurements.
We hypothesized that the elastic modulus of this cementless press-fit socket would lead to a physiological stress transfer that diminishes the effect of stress shielding.

Methods:

This study was performed in compliance with the declaration of Helsinki for medical research involving human subjects. The inclusion for this single-center, prospective cohort study, was conducted between 2008 and 2009 at the Sint Maartenskliniek, Nijmegen, The Netherlands. The study was approved by the local ethical committee Arnhem-Nijmegen (reg. no 2007294 24-01-2008). Patients were followed for 2 years. The inclusion criteria were unilateral primary osteoarthritis and on the waiting list for total hip replacement, BMI < 30, age between 18 and 70 years, and written informed consent. Patients with secondary osteoarthritis, previous acetabular surgery, pregnancy, bone metabolism disorders and anti-osteoporotic medications were excluded from the study.

Surgical technique

Two senior orthopedic surgeons performed all operations. Prophylactic third-generation cephalosporins were given to all patients. All arthroplasties were performed using a postero- lateral approach in a clean-air operating theater with laminar flow. Reaming of the acetabulum was undersized by 1.6 mm to achieve adequate press-fit. The RM press-fit socket (Mathys AG, Bettlach, Switzerland) is an all-polyethylene socket with a titanium-particle coating. The socket has a hemispherical monoblock design with a flatted pole and is made from nitrogen-radiated sterilized UHMW (ISO 5834-1+2) polyethylene. (Figure 1)

A cementless, grit-blasted, titanium-alloy (Ti6Al4V ISO 5832-3) CLS Spotorno femoral stem (Zimmer, Warsaw, IN) was used in all cases. In all patients, a 32-mm ceramic (Al_2O_3) head on polyethylene articulation was used.

All patients were mobilized on the first postoperative day and direct full weight bearing was allowed using crutches during the early postoperative rehabilitation period supervised by a physiotherapist. All patients received nadoparine for 6 weeks as thromboprofylaxis.

Bone mineral density measurement

During the first postoperative week a baseline computer tomography (CT) scan was made. Follow-up CT images were taken during the outpatient clinic visit at 6 and 24 months. A conventional CT scanner (Toshiba RXL Aquilion 32) with a standardized scanning protocol (135 Kv, 200 mA) with 1-mm slices at 10 mm intervals was used. (Figure 2a and b) In total 6 axial scans were performed starting 10 mm above the socket. The contra-lateral side was used as a control. One author (DP) determined the region of interest separately for cancellous and cortical bone at each level and performed BMD measurements using specialized BMD software (Toshiba BMD software) (Figure 2c). A phantom containing five defined calcium hydroxyapatite markers, positioned below the patient, was used to calibrate and measure the cortical and cancellous BMD values (mg/cm^3). The BMD was determined in all six slices on the prosthetic side for all tomography scans (baseline scan, 6 months and 24 months), and in three slices (1, 3 and 6) on the control side for the baseline scan and 24 months follow-up.

Clinical outcome

The Harris hip score (HHS) and the Oxford Hip Score (OHS) were determined preoperatively and at each clinical follow-up (2 months, 6 months, 12 months and 24 months). Pain scores were measured using the Visual Analog Scale (VAS). All adverse events and complications were recorded and analyzed, to monitor the safety of the technique used.

Statistical analysis

Normality of BMD was checked with a Shapiro-Wilk test and visually inspected with Q-Q plots. To test for changes in BMD in the different slices over time, repeated measures ANOVAs with the factors SLICE x TIME were performed on the absolute BMD data for both cancellous and cortical bone on the side of the prosthesis. To evaluate differences in BMD changes between prosthetic and control side, separate ANOVAs with the factors SIDE x SLICE x TIME were performed on the BMD of both cancellous and cortical bone on the slices that were available in the control side. If appropriate, post hoc analyses on significant main and interaction effects were performed with a Bonferroni correction for multiple comparisons.
Changes in clinical measures (OHS, HHS, and VAS pain score) over time were evaluated with a nonparametric Friedman test and post hoc analyses were performed with a Wilcoxon signed-rank test with a Bonferroni correction.
The limits of reproducibility of the BMD measurement were calculated using Bland and Altman's statistical method (Bland et al 1986) in 10 random samples and were 57.2 mg/cm^3 and 80.8 mg/cm^3 for cancellous and cortical bone, respectively. Statistical analyses were performed using SPSS (19.0.0) and MATLAB R2010b, with $p<0.05$ considered statistically significant.

Results:

25 patients were enrolled in this study. Due to difficulties of proper CT scan alignment in one patient, slices were not comparable during analysis. Therefore, this patient was removed from further analysis. The study demographics are presented in Table 1.
Because patients were aligned based on the prosthetic side, slice alignment for the control side was not always perfect. Due to this imperfect alignment we excluded the baseline or 24 months follow up measurement of the most cranial slice (slice nr 1, 20 mm above de socket) on the control side in 10 patients during our analysis.

Cancellous bone

A decrease in BMD over time was seen in the cancellous bone in all six slices on the prosthetic side (Figure 3). At six months follow-up the decrease was between -9.6% and -28.6% in respect to the baseline BMD values (Table 2). At 24 months follow-up, BMD decreased even further to levels between -13.8% and -35.3%. These effects were indicated by a significant main effect of time, $F(2,44)=61.9$, $p<0.001$; post hoc tests showed that BMD at six and 24 months follow-up was lower than baseline level. Furthermore, BMD at 24 months follow-up was lower compared to the six months follow up.

Differences in BMD between slices were seen at all time-points $F(5,110)=17.3$, $p<0.001$. BMD in the most cranial slice (Figure 2) was higher than in the other slices. BMD in slice 2 was higher than in slice 3, 4 and 5.

For the comparison of BMD between the prosthetic and the control side, slice 3 and 6 were used. Effects of side were different for the two time-points, indicated by an interaction between side and time, $F(1,23)=37.0$, $p<0.001$. In the baseline measurement, no difference between BMD on the prosthetic and control side was found, $F(1,23)=1.4$ (n.s.). In the 24 months follow-up measurement, the control BMD was higher than the BMD at the prosthetic side, $F(1,23)=19.1$, $p<0.001$. For both the prosthetic, $F(1,23)=92.8$, $p<0.001$, and control side, $F(1,23)=7.1$, $p=0.014$, the BMD decreased over time.

Cortical bone

In the cortical bone, changes over time were between 0.2% and -5.4% at six months follow-up and between 4.8% and -4.9% at 24 months follow-up (Figure 4 and Table 2). The six slices showed different patterns of changes in BMD over time, indicated by an interaction between slice and time, $F(10,220)=2.1$, $p=0.026$. However, no direct effect of time was found.
When looking at BMD in the prosthetic and control slices, effect of side and time were different for two slices (3 and 6): each slice showed a different pattern of BMD change between the sides and time points. This was indicated by an interaction between slice, side and time, $F(1,23)=4.7$, $p=0.041$. Therefore, changes were evaluated per slice. In slice 3, differences between prosthetic and control BMD changed over the two time-points, indicated by an interaction between side and time, $F(1,23)=7.6$, $p=0.011$. In the baseline BMD, no difference was found between the prosthetic and control BMD, $F(1,23)=0.1$ (n.s.).
In contrast, in the 24 month follow-up measurement, the BMD in the control side was higher than in the prosthetic side, $F(1,23)=10.6$, $p=0.004$. At Baseline and after 24 months, slice 6 showed a higher BMD value compared to the prosthetic side, $F(1,23)=44.9$, $p<0.001$.

Clinical results

Hip function improved over time as assessed by both the OHS, $\chi^2(4)=47.9$, $p<0.001$, and the HHS, $\chi^2(4)=54.8$, $p<0.001$. Post hoc analysis indicated that hip function improved after surgery and during recovery (Table 3). After six months hip function stabilized. Furthermore, VAS pain scores decreased over time, $\chi^2(4)=49.9$, $p<0.001$. Post hoc test revealed a decrease of pain after surgery (see Table 3). There were missing values for the HHS for two patients, for the OHS for four patients, and for the VAS for three patients.

Discussion:

In this prospective cohort study we found a significant decline of cancellous BMD (-14 to -35%) and a steady state of cortical BMD (4.8 to - 4.9%) surrounding the elastic press fit cup during the follow up period. The main decline was seen during the first 6 months after implantation. Because the mean acetabular BMD showed a decline in the peri-acetabular bone during our follow up, our study hypothesis could not fully be confirmed.

Although there are several papers reporting contradicting views on the relevance of acetabular stress shielding [Huo 2008, Meneghini 2010, Kress 2011, Moore 2006, Stepniewski et al 2008], surgeons who perform hip revision surgery, know that substantial bone loss, especially of pelvic bone, is the most challenging problem during hip revision surgery. Especially in high demanding patients with long-term expectations, stress shielding could be of clinical relevance [Digas 2006] and result in peri-acetabular bone adaptation.

A quantative CT measurement is able to differentiate between cancellous and cortical bone. [Schmidt 2000, Pitto 2007] Because of the expense and radiation, it has been used in a few papers to quantify, cortical and cancellous bone adaptation in acetabular bone. [Meneghini 2009, Mueller 2009, Kress 2011]
In two published papers [Meneghini 2009, Mueller 2009], a reduction of BMD was revealed after the implantation of different types of acetabular components. In both studies, the more flexible implant showed a lesser decline of BMD during the follow up period. The press fit socket used in our study has an elasticity modulus comparable to bone.
The properties of this construct permit a physiological stress transmission onto the acetabular bone behind the socket and thus reducing the potential stress shielding effect. With this flexible socket we found the largest decrease of cancellous BMD in the region medial to the socket (35%). We observed the smallest decrease at the acetabular roof (14%), cranial to the socket inline with the stress vector crossing the acetabulum indicating stress transfer along the physiological stress lines. The increased caudal en decreased cranial cortical reaction is similar to the results found by the group from Germany [Kress 2011, Mueller 2007]. The basis of this reaction can be found by the press fit implantation of the socket with, in accordance with performed finite element analysis, the loading of the acetabular cortical rim. [Huiskes 1987]
Bone adaptation leading towards stress shielding could be a long-term process. The longest follow up on acetabular stress shielding was published in 2011. [Kress 2011] A fiber-mesh press fit socket was implanted and evaluated with BMD measurements during a ten-year follow up period. The authors anticipate that the BMD loss would be a continuous process. However in contrast to the stress-shielding hypothesis, cancellous bone density showed a steady state during the last 7-years follow up. [Kress 2011] Our data showed a lesser decline in BMD at the end of our two-year follow up period. This could potentially point towards stabilization in acetabular cancellous BMD especially in the cranial zones surrounding the socket. The cortical BMD seemed to stabilize at two years follow up.

On the contralateral side we also found a decline in cancellous BMD. Although being equal preoperatively, after 2 years follow-up the BMD in the control side was higher than the BMD in the prosthetic side. The explanation for this could be that during recovery mobilization and weight bearing is altered and that the implanted socket does alter the force distribution and therefore influences the bone density.

On the basis of our data, we are not able to validate our hypotheses as stated at the beginning of our investigation. A possible explanation for the absence of the expected prevention of stress shielding could be that stress transfer onto the surrounding acetabular bone not only depends on the socket elasticity but is also influenced by other factors such as socket geometry, hip biomechanics, socket position, fixation method, articulation and patient characteristics. Stress transfer and the process leading to stress shielding seems to be a multifactorial process in which bone adaptation is determined.

There are some limitations in this study; in this study we report short-term results on a phenomenon that could be a long-term process. However, in comparison to bone healing after fractures (de Jong 2014), short-term quantative CT measurements are able to provide relevant data on the bone remodeling process.
Due to slice alignment on the prosthetic side, the cranial slice on the control side was missing in some cases. We feel this limitation is of no consequence on the outcome of our study, because our primary focus was the change of acetabular BMD surrounding the socket. In all patients, the acquired slices were surrounding the socket and its contralateral counterpart.
Limitations of reproducibility concerns can be raised when using software, measuring BMD surrounding acetabular components. In this study BMD measurements were performed by one investigator to reduce error and enlarge the factor of repeatability.
The limit of reproducibility was larger than (in cortical bone) or was around (in cancellous bone) the differences found. Hence, we cannot exclude reproducing errors for causing the changes in BMD. However, as mentioned before the results are in agreement with previous studies [Kress 2011, Meneghini 2010 Mueller 2009, Pitto 2008, Mueller 2007, Field 2006, Mueller 2007, Mueller 2006, Wright 2001, Wilkinson 2001], so the results might represent a true effect.
In conclusion, we observed a moderate reduction of cancellous BMD and a steady state of cortical BMD 6 to 24 months after implantation of an elastic cementless monobloc press-fit socket with properties resembling the elastic modulus of bone. Based on the results of this study, there is no statistical significant support for the hypothesis that an elastic press fit socket could prevent acetabular stress shielding. Further follow up is necessary to determine the long-term effect of the elastic properties on stress shielding, osteolysis and socket survival.

Literature:

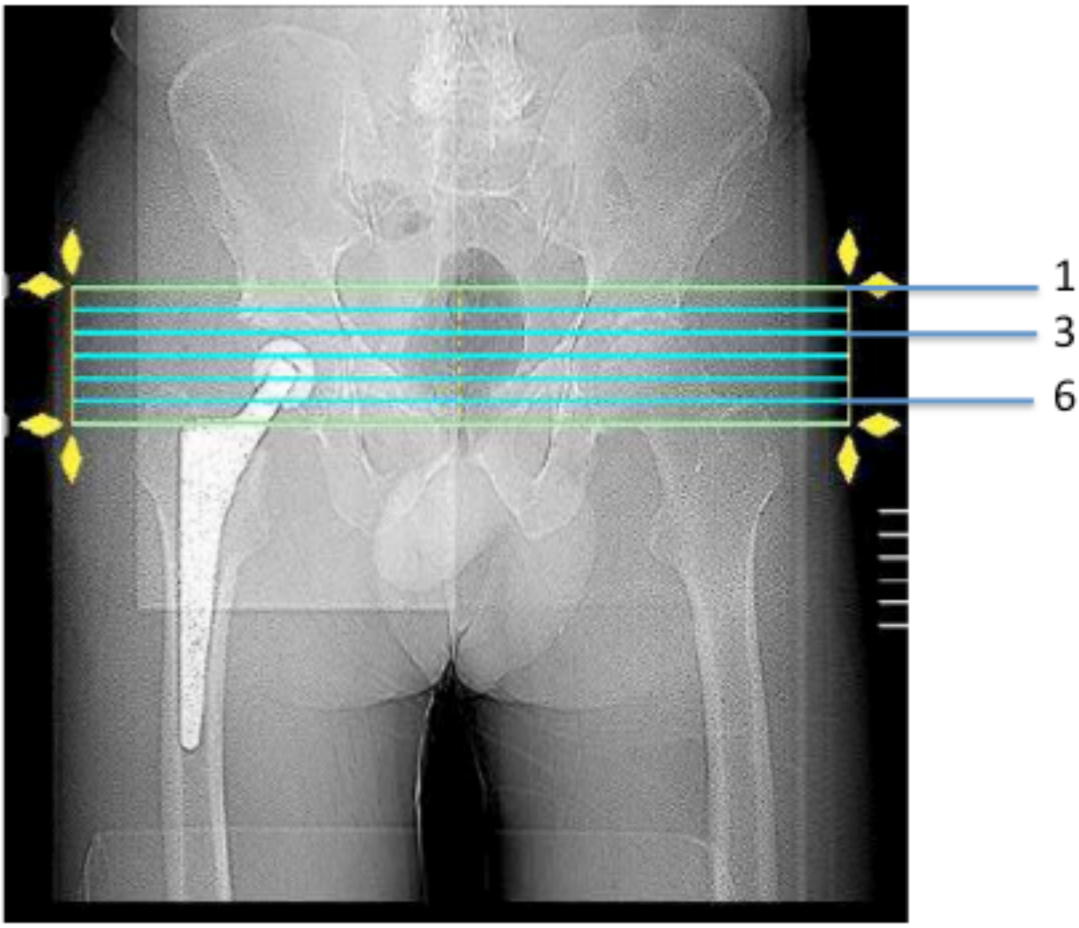
1. Baad-Hansen T, Kold S, Nielsen PT, Laursen MB, Christensen PH, Soballe K.Comparison of trabecular metal cups and titanium fiber-mesh cups in primary hip arthroplasty: a randomized RSA and bone mineral densitometry study of 50 hips. Acta Orthop. 2011;82:155-60.
2. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;1:307-310.
3. Caton J, Prudhon JL. Over 25 years survival after Charnley's total hip arthroplasty. Int Orthop. 2011;35:185-8.
4. Digas G, Kä̈rrholm J, Thanner J. Different loss of BMD using uncemented press-fit and whole polyethylene cups fixed with cement: repeated DXA studies in 96 hips randomized to 3 types of fixation. Acta Orthop 2006;77: 218–226.
5. Engh CA Jr, Young AM, Engh CA Sr, Hopper RH Jr. Clinical consequences of stress shielding after porous-coated total hip arthroplasty. Clin Orthop Relat Res. 2003;417:157-63.
6. Engh CA, McGovern TF, Schmidt LM. Roentgenographic densitometry of bone adjacent to a femoral prosthesis. Clin Orthop Relat Res. 1993;292:177-90.
7. Eskelinen A, Remes V, Helenius I, Pulkkinen P, Nevalainen J, Paavolainen P.Total hip arthroplasty for primary osteoarthrosis in younger patients in the Finnish arthroplasty register. 4,661 primary replacements followed for 0-22 years. Acta Orthop. 2005;76:28-41.
8. Field RE, Cronin MD, Singh PJ, Burtenshaw C, Rushton N. Bone remodeling around the Cambridge cup: a DEXA study of 50 hips over 2 years Acta Orthop. 2006;77:726-32.
9. Huiskes R. Finite element analysis of acetabular reconstruction. Noncemented threaded cups. Acta Orthop Scand. 1987;58:620-5.
10. Huiskes R, Weinans H, van Rietbergen B. The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials. Clin Orthop Rel Res. 1992;274:124-34.
11. Huiskes R. Finite element analysis of acetabular reconstruc- tion. Noncemented threaded cups. Acta Orthop Scand 1987;58:620–625.
12. Huo MH, Parvizi J, Bal BS, Mont MA, What's new in total hip arthroplasty, J Bone Joint Surg. 2008;90:2043-2055.
13. de Jong JJ, Willems PC, Arts JJ, Bours SG, Brink PR, van Geel TA, Poeze M, Geusens PP, van Rietbergen B, van den Bergh JP. Assessment of the healing process in distal radius fractures by high-resolution peripheral quantitative computed tomography. Bone 2014;64:65-74.
14. Kim YH, Yoon SH, Kim JS. Changes in the bone mineral density in the acetabulum and proximal femur after cementless total hip replacement: alumina-on-alumina versus alumina-on-polyethylene articulation. J Bone Joint Surg. 2007;89:174-9.
15. Kress AM, Schmidt R, Vogel T, Nowak TE, Forst R, Mueller LA. Quantitative computed tomography-assisted osteodensitometry of the pelvis after press-fit cup fixation: a prospective ten-year follow-up. J Bone Joint Surg. 2011;93:1152-7.
16. Laursen MB, Nielsen PT, Søballe K. Bone remodelling around HA-coated acetabular cups: a DEXA study with a 3-year follow-up in a randomised trial. Int Orthop. 2007;31:199-204.
17. Levenston ME, Beaupré GS, Schurman DJ, Carter DR. Computer simulations of stress-related bone remodeling around noncemented acetabular components. J Arthroplasty. 1993;8:595-605.

18. Meneghini R, Ford K, McCollough C, Hanssen A, Lewallen D, Bone remodeling around porous metal cementless acetabular components. J Arthroplasty 2010;25:741-747.
19. Moore MS, McAuley JP, Young AM, Engh CA Sr.Radiographic signs of osseointegration in porous-coated acetabular components. Clin Orthop Relat Res. 2006;444:176-83.
20. Mueller LA, Voelk M, Kress A, Pitto RP, Schmidt R. Progressive cancellous and cortical bone remodeling after press-fit cup fixation: a 3-year follow-up. Clin Orthop Relat Res. 2007;463:213-20.
21. Mueller LA, Schmidt R, Ehrmann C, Nowak TE, Kress A, Forst R, Pfander D.Modes of periacetabular load transfer to cortical and cancellous bone after cemented versus uncemented total hip arthroplasty: a prospective study using computed tomography-assisted osteodensitometry. J Orthop Res. 2009;27:176-82.
22. Mueller LA, Nowak TE, Mueller LP, Schmidt R, Ehrmann C, Pitto RP, Pfander D, Forst R, Eichinger S. Acetabular cortical and cancellous bone density and radiolucent lines after cemented total hip arthroplasty: a prospective study using computed tomography and plain radiography. Arch Orthop Trauma Surg. 2007;127:909-17.
23. Mueller LA, Kress A, Nowak T, Pfander D, Pitto RP, Forst R, Schmidt R.Periacetabular bone changes after uncemented total hip arthroplasty evaluated by quantitative computed tomography. Acta Orthop. 2006;77:380-5.
24. Pakvis D, Luites J, van Hellemondt G, Spruit M. A cementless, elastic press-fit socket with and without screws. Acta Orthop. 2012;83:481-7.
25. Pitto RP, Mueller LA, Reilly K, Schmidt R, Munro J. Quantitative computer-assisted osteodensitometry in total hip arthroplasty. Int Orthop. 2007;31:431-8.
26. Pitto RP, Bhargava A, Pandit S, Munro JT. Retroacetabular stress-shielding in THA.Clin Orthop Relat Res. 2008;466:353-8.
27. Schmidt R, Freund J, Hirschfelder H, Pitto RP. Osteodensitometry in uncemented total hip arthroplasty using computertomography. Biomed Tech. 2000;45:70-4.
28. Schmidt R, Muller L, Kress A, Hirschfelder H, Aplas A, Pitto RP.A computed tomography assessment of femoral and acetabular bone changes after total hip arthroplasty. Int Orthop. 2002;26:299-302.
29. Stepniewski AS, Egawa H, Sychterz-Terefenko C, Leung S, Engh CA Sr. Periacetabular bone density after total hip arthroplasty a postmortem analysis. J Arthroplasty. 2008;23:593-9.
30. Wilkinson JM, Peel NF, Elson RA, Stockley I, Eastell R. Measuring bone mineral density of the pelvis and proximal femur after total hip arthroplasty. J Bone Joint Surg. 2001;83:283-8.
31. Wolff J. "The Law of Bone Remodeling". Berlin Heidelberg New York: Springer, 1986 (translation of the German 1892 edition).
32. Wright J M, Pellicci P M, Salvati E A, Ghelman B, Roberts M M, Koh J L. Bone density adjacent to press-fit acetabular components. A prospective analysis with quantitative computed tomography. J Bone Joint Surg. 2001;83:529-36.
33. Zingler K, Haeberle L, Kress A, Holzwarth U, Forst R, Mueller LA, Schmidt R. Comparison of cortical and cancellous bone remodeling of the pelvis after press-fit cup total hip arthroplasty dependent on patient and prosthesis-specific characteristics: a computed tomography-assisted osteodensitometry study in vivo. Biomed Tech (Berl). 2011.

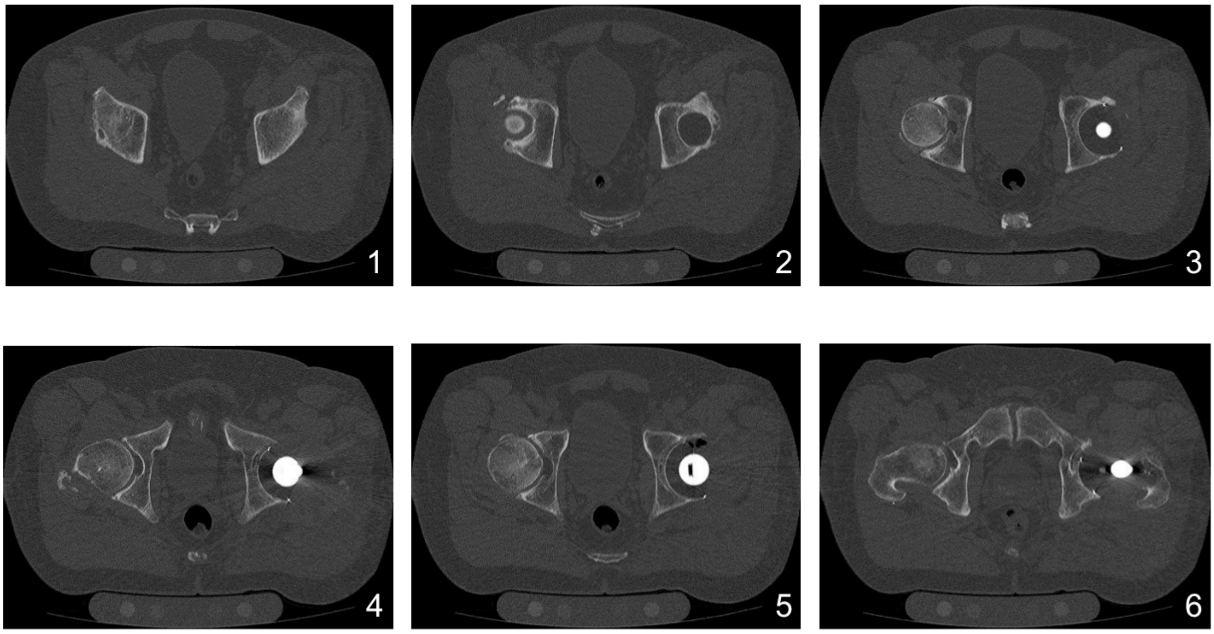
Figure 1 RM cementless press-fit socket (Mathys AG, Bettlach, Switzerland)

Figure 2 a Scanogram, **b** sequential CT slices surrounding the acetabular component, **c** measurement cancellous BMD.
In total 6 axial scans were performed starting 10 mm above the socket parallel to the horizontal teardrop line.

2a



2b



2c

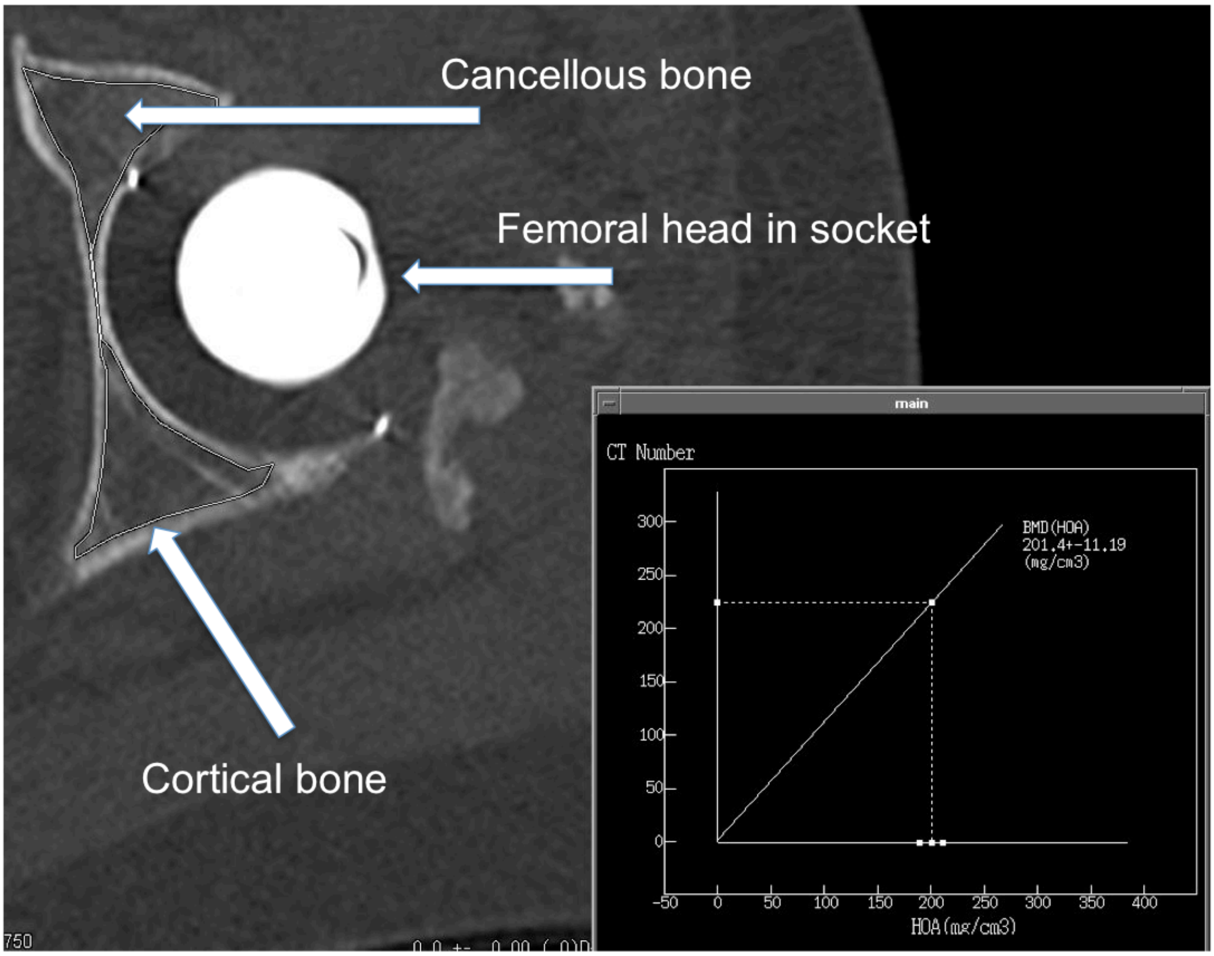

Cancellous bone
Femoral head in socket
Cortical bone
main
CT Number
BMD(HOA)
201.4+-11.19
(mg/cm3)
HOA(mg/cm3)
750

Figure 3. Box plots of the cancellous bone mineral density in the six slices for the baseline (PostOp0m), six (PostOp6m) and 24 (PostOp24m) months follow-up measurement. Blue bars indicate the BMD in the prosthetic hip; red bars indicate the BMD in the contra-lateral hip. The median is indicated by the central circle, the end of the thick line are the 25th and 27th percentile and the thin line extends to the most extreme values that are not considered outliers (indicated by a circle below or above the line).

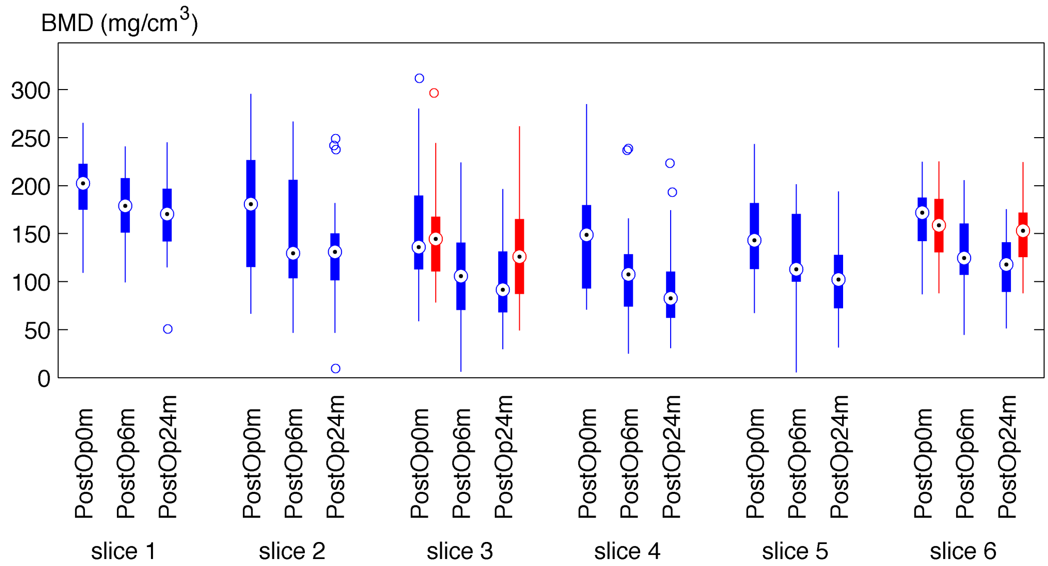


Figure 4 Box plots of the cortical bone mineral density in the six slices for the baseline (PostOp0m), six (PostOp6m) and 24 months (PostOp24m) follow-up measurement. Blue bars indicate the BMD in the prosthetic side; red bars indicate the BMD in the control side.

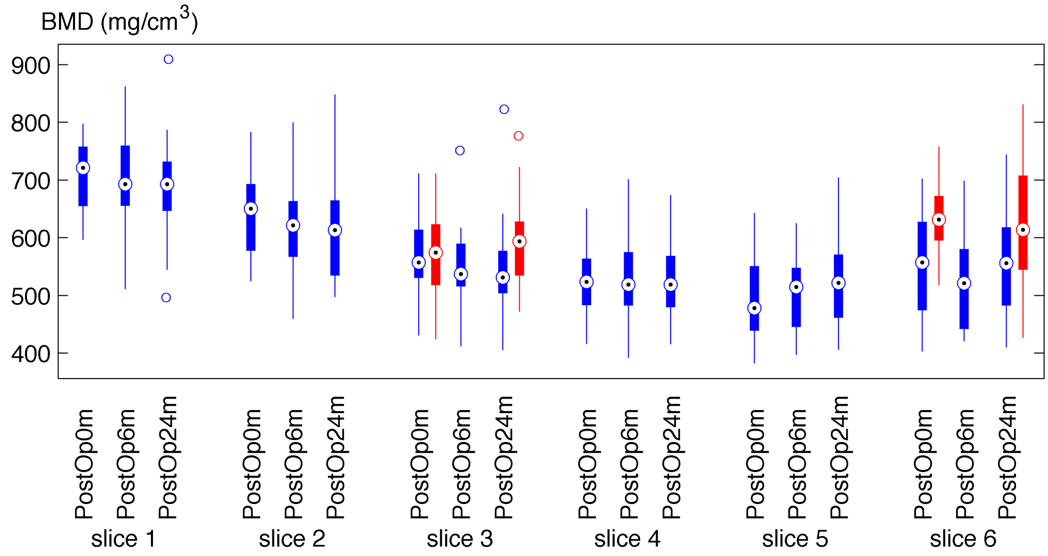


Table 1 Study demographics

Number of patients	24
(M/F)	7/18
Age (Mean, years) (SD) (Range)	64 (4) (56-71)
BMI (Mean, kg) (SD) (Range)	27 (3.1) (23-36)

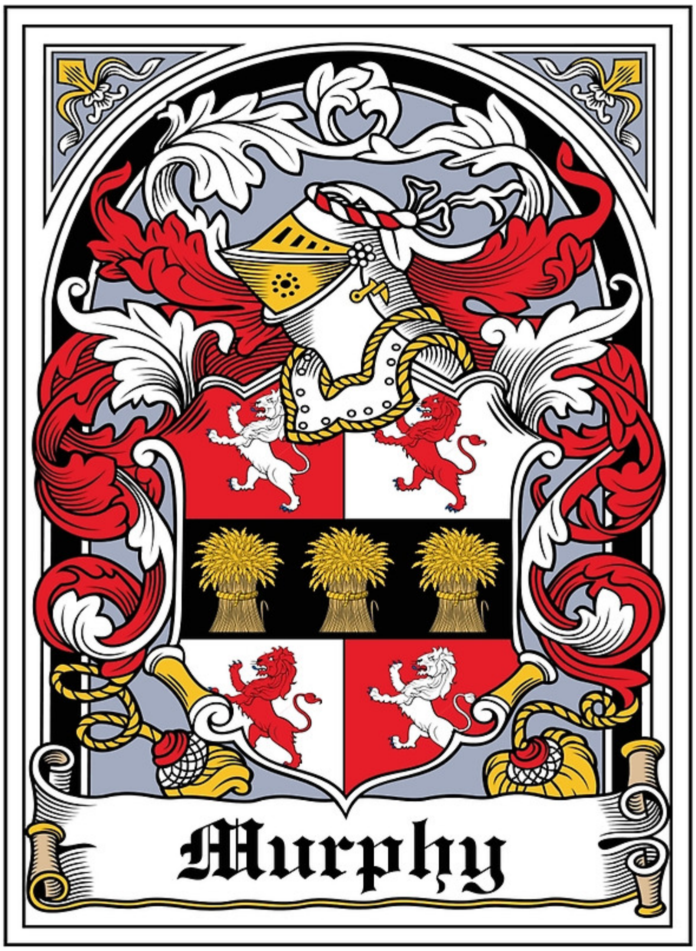
Table 2 BMD changes (%) relative to Postop 0m.

	Cancellous bone			Cortical bone		
	PostOp 6m	Post Operative 24m		Post Operative 6m	Post Operative 24m	
	Prosthetic	Prosthetic	Control	Prosthetic	Prostheti c	Control
1	-9.6	-13.8		-1.1	-2.5	
2	-17.0	-26.0		-3.9	-4.9	
3	-28.6	-35.3	-11.6	-2.6	-3.5	4.9
4	-22.6	-31.9		-0.7	-0.2	
5	-16.0	-31.0		0.2	4.8	
6	-20.2	-30.8	-4.8	-5.4	-0.6	-0.3

Table 3 Clinical scores. Median values and range (in brackets) are given for the OHS, HHS and VAS.

	Pre Op	Post Op 2	p[a]	Post Op 6	p[a]	Post Op 12	p[a]	Post Op 24	p[a]
OHS	24 (15-34)	34 (14-47)	0.035	45 (11-48)	0.001	47 (22-48)	<0.001	45 (19-48)	<0.001
HHS	61 (39-81)	77 (47-100)	0.032	95 (32-100)	0.001	98 (65-100)	<0.001	96 (57-100)	<0.001
VAS	50 (6-87)	12.5 (0-50)	0.001	0 (0-80)	0.001	0 (0-70)	<0.001	0 (0-70)	<0.001

[a] p-values are derived from the comparison with Pre Op with the Wilcoxon signed-rank test


Murphy

Chapter 8: Summary

Chapter 9: Discussion

Chapter 10: Samenvatting

Chapter 11: Thanks to all (Dankwoord)

Chapter 12: Curriculum Vitae

Chapter 8:

Summary (English)

Scientists, orthopedic surgeons and orthopaedic companies have combined their knowledge since the 1960's to achieve good long-term survival after the implantation of a total hip arthroplasty (THA). However, at present patients have increasing expectations of orthopedic treatment and therefore there may be a trend towards more liberal indications for THA and subsequent inferior success rates for these high demanding patients. On the other hand, because the level of knowledge of hip surgeons has considerably improved, more patients can be safely treated to achieve the desired quality of life.
The consequence of operating on younger patients is that it may result in an increase of expected revisions on the longer term. The acetabular component is and will most likely remain the main reason to revise the failing prosthetic system. Besides hip tribology and biomechanics, the greatest challenge for hip specialists in the future will be the quality of the remaining periprosthetic bone and the treatment of bone defects during revision surgery.
This thesis has focused on the survival, stability and acetabular bone remodeling specifically after the implantation of an 'elastic' cementless socket in comparison to other types of sockets.

Chapter 1 contains a historical overview of total hip replacement. We point towards the acetabular component as the main reason for a revision arthroplasty and describe several factors that are responsible for revision surgery.
In 1892 Julius Wolff described what later became known as 'Wolff's Law' in the book: Das Gesetz der Transformation der Knochen. In this book he describes the relationship between bone quality and the force and stress levels within the bone. Wolff's law states that bone will adapt to the exposed loads. If loading on a particular bone increases, the bone will remodel itself over time to become stronger or bone will weaken when loads are lower than physiological levels.
Acetabular bone weakening after the implantation of a socket has been described in literature and is attributed to the rigidity of the sockets. The rigidity of the implant would lead to shielding the bone from stress (referred to as 'stress shielding'). The lower bone stresses behind a more rigid socket will alter and weaken the integrity of bone, which leads to our ultimate hypothesis; a cup with elastic properties close to bone will reduce stress shielding and the decline of acetabular bone mineral density (BMD) resulting in a a reduction of acetabular osteolysis after implantation of an acetabular component.

Since the development of the modern hip arthroplasty by Charnley in 1962, THA has been a very successful orthopedic procedure. The basis for this success has been the cemented hip arthroplasty. However, during the 1970's cementless arthroplasties became more interesting because of the revisions were wrongly attributed to the cement particle disease. Currently there is still a large debate which fixation method (cemented or cementless) is optimal.
Up till now the optimal fixation method of the acetabular component has not yet been established. In ***chapter 2*** we performed a systematic review using the Medline and Embase databases to find evidence for the superiority of cemented or cementless acetabular components on short- and long-term clinical and radiological parameters.

Our search strategy revealed several randomized controlled trials (RCT) and non-RCT studies in which cemented and cementless acetabular components were compared. A best evidence analysis for complications, wear, osteolysis, migration and clinical scores showed no superiority for either cemented or cementless sockets in the RCTs.
A best evidence analysis for non-RCT studies revealed less osteolysis, superior stability properties and superior survival for aseptic loosening for cementless sockets. However, wear and overall survival favored the cemented sockets. Therefore, we believe that surgeons should base their choice on literature available on the specific sockets combined with their personal experience and preference.

In conclusion of chapter 2 we found no evidence of superiority when comparing cementless and cemented sockets. We recommend that an orthopedic surgeon should choose an established cemented or cementless socket for THA based on patient characteristics, knowledge, experience and preference.

The survival of acetabular components depends on several short and long-term factors: wear, osteolysis and septic or aseptic loosening. Osteolysis seems to be the main cause for concern in cementless arthroplasties. Acetabular osteolysis results from particle debris and segmental unloading of acetabular bone by sockets. In ***chapter 3*** we investigated a cementless, elastic monoblock socket with regard to acetabular osteolysis and aseptic loosening in a cohort of young patients (younger than 50 years). The overall survival rate at 14 years was 80% with a 98% survival rate for aseptic loosening. The mean polyethylene wear rate was 0.11 mm/y. Progressive acetabular osteolysis was seen in 3% of all patients evaluated. In this study we found low pelvic osteolysis rates, acceptable overall wear rates, a satisfying overall survival rate and an excellent survival rate for aseptic loosening. We expect that ongoing tribology developments and knowledge concerning acetabular bone adaptations behind acetabular implants will further reduce wear and osteolysis rates and elongate survival rates of cementless sockets.

Chapter 3 shows good clinical and radiological results when using cementless elastic monobloc sockets in patients younger than 50 years.

Besides tribological developments, using highly cross-linked polyethylene (PE) or ceramic on ceramic bearings to reduce particle wear and acetabular osteolysis, some researchers point towards the reduction of stress shielding as another potential mechanism to reduce long-term weakening of the acetabular bone structure. Relative to cemented sockets, cementless sockets are usually stiffer and therefore are more likely to alter the stress levels in the acetabular bone. Femoral stress shielding is a generally identified causative failure mechanism for femoral osteolysis and revision surgery. On the acetabular side, this mechanism has been identified to a much lesser extent. However, some authors state that acetabular stress shielding may be a failure mechanism of acetabular constructs promoting osteolysis, aseptic loosening and failure.

To investigate this hypothesis, in ***chapter 4***, we used three-dimensional finite element analysis (FEA) to evaluate the effect of flexible sockets on acetabular stress shielding. The sockets were assumed to be made of (1) full PE, (2) PE with a metal bearing and (3) a PE insert with a metal backing (representing a traditional implant). We compared the strain energy density and interfacial micro-motions between bone and cementless sockets during a simulated walking loading condition. In our FEA model, the most elastic socket (case 1) showed the highest levels of micro-motion during walking (400 μm). The most rigid socket (case 3) showed smaller areas of high micro-motions.
Assuming a threshold for ingrowth of 50 microns, the flexible cup showed an ingrowth area of almost 40%, whereas the two other cases showed stable areas covering 60% of the total bone-component interface. Furthermore, we found that the insertion of the cementless socket generates rather high strain levels directly around the implant as compared with the intact case, which has a horse- shoe shaped cartilage layer in the acetabulum. This difference of load transfer between the studied cases was hardly detectable. Hence, the stiffness did not alter the stress patterns around the implants to a considerable level; a more flexible implant resulted in only slightly higher strain levels. Bone strains at a distance beyond 1.5 mm from the cup showed physiological values and were not affected by the stiffness of the implant.

The study showed that physiological strain patterns are not obtained in the direct peri-prosthetic bone, regardless of the stiffness of the material.

Our FEA studied showed high levels of interfacial micro motions of the more flexible socket, which could interfere with osseointegration and long term stability. When considering elasticity (flexibility) of a socket as a potential answer to acetabular stress shielding and resulting osteolysis we investigated the in-vivo stability of a press fit cementless titanium coated elastic monoblock socket and the influence of supplementary screw fixation in ***chapter 5***. We performed a randomized controlled trial on 37 patients in whom we implanted a cementless press-fit socket. The socket was implanted with and without additional screw fixation to determine the stability of an elastic press fit socket. Using radiostereometric analysis we determined the stability of the socket with a 2-year follow-up.
The sockets without screw fixation showed a statistically significant higher proximal translation compared with the socket with additional screw fixation. However, this higher migration was considered to be below the clinically relevant threshold. The numbers of migrating sockets were not different between the two groups. After 2 years follow-up there were no clinical relevant differences between the group with and without the additional screw fixation regarding the clinical scores.

Based on the data from chapter 5 we can conclude that there is no added value of additional screw fixation for the cementless press fit elastic socket with an excellent two-year survival.

There are several cementless sockets available to surgeons, each with different elastic modalities and fixation methods. Press fit sockets are implanted with a certain amount of pre-strain on the surrounding acetabular bone which interferes with the local bone metabolism. The strain on the surrounding bone is different when implanting a socket that is implanted using a screw mechanism.
A randomized controlled trial was performed in ***chapter 6***, to evaluate acetabular BMD changes after a press fit, rigid hip resurfacing socket (cobalt-chromium) versus an established threaded socket (titanium cup and polyethylene-metal-inlay insert). The BMD, measured using dual-energy X-ray absorptiometry (DEXA) in five separate acetabular regions of interest (ROI), was prospectively quantified at the preoperative stage and until 24 months post operatively. In contrast to our expectations, acetabular BMD was better preserved around the rigid cobalt-chromium press fit socket than around the more elastic titanium threaded socket.

The conclusion of chapter 6 was that we could not find evidence for the protective effect on stress shielding when comparing a more rigid press fit cup and a more elastic threaded socket using DEXA measurements during follow up.

The bone density evaluation using DEXA provides investigators with a 2D measurement regarding a 3D structure without the differentiation between cortical and cancellous bone. When using quantitative computer tomography (CT) measurements both acetabular cancellous and cortical bone can be evaluated in a 3D manner surrounding the socket. Although this provides investigators with sensitive data, quantitative CT scanning is only used in scientific studies due to the increased radiation levels the patients are exposed to.

In ***chapter 7*** we studied the change of acetabular BMD using quantitative CT cancellous and cortical bone mineral density measurements after the implantation of a more elastic socket. We performed a single centre prospective trial on 25 patients in whom we implanted a cementless press-fit socket. Using quantitative CT bone mineral density measurements, we determined the change of bone mineral density surrounding the acetabular component during the 2-year follow up period.
We found a significant decline of cancellous BMD and a small decline of cortical BMD surrounding the cranial region of the elastic press fit cup during the follow up period. The main decline was seen during the first 6 months after implantation. During the second year the rate of decline of BMD diminished.
We observed a moderate reduction of cancellous BMD and a slight increase of cortical BMD in the period of 6 to 24 months after implantation of an elastic cementless press-fit socket.

After reviewing our results in chapter 7 we found no evidence that an elastic press fit socket could prevent acetabular stress shielding when measuring the BMD with a quantitative CT scan.

Chapter 9:

Discussion:

Total hip arthroplasty (THA) is one of the greatest surgical innovations of the last 60 years. The growing numbers, needs and life expectancy of people who require hip reconstruction demand the optimization of all factors leading towards a longer survival of THA.

Acetabular survival and fixation method:
Throughout the years there has been debate on which method of fixation for a socket should be regarded as superior. Although each type of fixation has its pros and cons, in our review, presented in chapter two, we found no conclusive evidence for superiority of any type of socket fixation. The often described superior survival for cemented sockets can be explained by the fact that often comparisons are made between "old", frequently used, and well evolved cemented sockets and the "newer" less frequently used, yet to evolve, cementless sockets. [1,2]
Comparison between cemented and cementless sockets in the Swedish registry may be regarded as somewhat biased. Comparisons are made, in a country with a historical preference and experience with cemented hip arthroplasty, between the 10 most common cemented (+ 100.000 components) and cementless (6800 components) sockets. [1] Although the authors found the same reasons for revision between cemented and cementless sockets and the top 5 of both cemented and cementless sockets showed no difference in risk of revision they deemed the cementless socket as the Achilles tendon of uncemented THA.
Another bias in reports on superior fixation methods can be found in the compilation of results found in high and low volume centers. Centers with lower case loads and experience will distort and confound the lower complication and mortality rates reported by high caseload and experienced centers. [3]

There is extensive research showing good long-term results for both cemented and cementless sockets. [4,5] In 2012 the Dutch Orthopedic Association (NOV) published a list of cementless and cemented components for hip arthroplasty and graded each as 1A, 1B or 2 according to available data derived from long-term research and (inter) national registry data. Our British colleagues have done the same with the orthopedic data evaluation panel (ODEP, www.odep.org.uk). Since 2000 they provided the international orthopedic community with an extensive database based on the National Institute of Healthcare and Clinical Excellence (NICE) guidelines, which the hip surgeon can use to choose a reliable implant to optimally treat patients.
The NICE guidelines postulate a revision rate of 10% or less at 10 years, or performance compatible with that benchmark at three years for hip arthroplasties. When reviewing the ODEP database there are both cemented and cementless sockets with good ratings according to the NICE criteria. When following the NICE guidelines and the related ODEP qualifications and when familiar with the options of both fixation methods, the surgeon is provided with evidence and recommendations to treat patients with osteoarthritis of the hip dictated by the individual circumstances.

Chapter three concludes that the cementless socket has an excellent aseptic survival and a good overall survival at 14 years which is in accordance with published literature and corroborates the results of the Non RCT studies found in chapter two. Hence, the cementless sockets showed good long-term aseptic survival. The clinical findings of the elastic socket used in our study, complies with the described NICE criteria. Long-term studies are favored to determine survival, however short-term radiostereometric analysis (RSA) studies can predict long-term survival of implanted sockets. In chapter five, using RSA measurements, we predict a good long-term fixation of the cementless press fit RM socket, which is an evolutionary design of the socket studied in chapter three.

In chapter one we described the aims for this thesis. Based on the results of the studies in chapters two and three, the information acquired using the ODEP, the Scandinavian registries and our own NOV hip advice list, we recommend hip surgeons to select a proven concept and a method of fixation with which they are familiar with in order to achieve the best results for their patients.
However, the perfect socket with optimal primary stability (chapter five), physiological stress transfer (chapters six and seven), optimal range of motion without increasing instability and no articulation wear, which is providing the patient with a life lasting solution, has not yet been established. Hence, the perfect socket does not exist! Therefore, surgeons need to explore refinement and consider new options to ultimately improve longterm outcome. New concepts should, after an extensive pre-clinical testing program, be tested in selected clinical studies using RSA to evaluate stability and CT measurements to evaluate wear and BMD changes.

Acetabular stress shielding:

Aseptic loosening is the most frequent reason for acetabular component revision. It is caused by several mechanisms such as inadequate primary stability and osteolysis of the surrounding acetabular bone, which leads to failure of the fixation of the acetabular component. There are several causes leading towards acetabular osteolysis. The main cause is the activation of macrophages and osteoclasts by wear debris through interleukin and tumor necrosis factor stimulation. [6] Another factor for periacetabular osteolysis, predominantely seen in cases of cementless sockets, is acetabular stress shielding. In acetabular stress shielding, the reduction of articular loads transmitted across the implant onto its surrounding bone causes acetabular osteolysis that may lead to loosening of the socket.

The basis of this thesis was derived from the idea that a cup with a modulus close to bone (approx 1GPA) would result in a more physiological force distribution onto the acetabular bone with the preservation of the acetabular bone stock.
Although our hypothesis primarily focused on socket elasticity, other factors such as bone BMD and positioning of the socket will also contribute to change in stress distribution, polyethylene (PE) wear and the subsequent osteolysis. [7-9]

Our aim for chapter four was to study the influence of the elastic properties of cups on acetabular stress shielding. Our finite element analysis (FEA) showed that with changes in elastic modulus of the sockets, no relevant changes in stress transfer across the acetabular bone occurred. The all-poly-socket showed the most physiological stress transfer onto the acetabular bone, although differences were small. The results obtained in chapter four affect our primary stress shielding hypothesis. Our results are, however, in agreement with Vasu and colleagues who performed an FEA using cemented sockets and found that stresses were seen on the medial wall and superior cancellous acetabular bone, comparable to the physiological stress distribution seen in a normal hip joint. [10] In a clinical study using cemented sockets, the authors reported the same stress distribution in the acetabulum. [11] Our results point towards the conlusion that a more rigid cementless socket showed no physiological stress transfer onto the acetabular bone. The explanation for the small but more physiological stress distribution onto the acetabular bone could be that a cemented polyethylene socket (low elastic modulus) is able to distribute the articular load in a more physiological manner through the surrounding bone cement without the press fit peripheral stresses [12], which are needed in cementless sockets.

Vasu and colleagues stated that the stresses dispersed through the cement mantle could also depend on the mantle thickness. [12] A decline in stress distribution onto the surrounding acetabular bone was seen in thicker cement mantles. [12] The study in chapter four showed that a more elastic press fit cementless socket produced a more physiological stress distribution compared to the more rigid metal backed press fit socket. Elastic material properties therefore alter the stress transfer onto the surrounding acetabular bone. However, our studies in chapter six and seven show that the clinical relevance of this alteration is probably quite low.

In chapter six we evaluated the change in bone mineral density after the implantation of two sockets each with a different design, elastic modulus and fixation technique. We compared bone mineral density (BMD) after the implantation of a press fit, rigid socket used in hip resurfacing and a less rigid conical shaped screw socket used in THA.
In theory, one could argue that the conically shaped more elastic screw cup should create a more physiological and uniformly distributed stress transfer onto the acetabular bone. This theory could not be supported by the results found in chapter six. The potential benefit of the lower elastic modulus could be counteracted by other aspects in cup design (geometrical shape, polar gap, material thickness, coating etc). Another explanation could be that the stress transduction through a large femoral head (hip resurfacing) is more physiological compared to a “standard” small head articulation. The compressive and tensile stresses when press fitting a hip resurfacing socket into the acetabular bone could lead to peripheral cortical hypertrophy and alter cortical density, which could also provide an explanation for the encountered BMD difference.

Bone adaptation is a long-term biological process. [13] The studies reported in chapter six and seven had a two-year follow up, which could be too short to fully acknowledge the long-term effect of a low elastic modulus socket on acetabular bone. Kress and colleagues published the longest clinical follow up on acetabular stress shielding in 2011. [14] The authors found a decline of bone mineral density in the surrounding acetabular bone, during the first three years after implantation of a cementless, more rigid, fiber mesh press fit socket. During the following period, up to ten-years after socket implantation, no further decline in BMD was observed. The mean decline of acetabular BMD found in chapter seven, using a more elastic socket, was somewhat lower compared to the study by Kress [14] using a more rigid socket; we therefore hypothesized that elasticity could have an effect on long-term bone remodeling. Further follow up of our study group is needed to evaluate the long-term effect of an elastic socket on acetabular BMD. Our results in chapter six and seven substantiated the results found in our FEA model described in chapter four. The alteration in stress distributions and subsequent changes in BMD after the implantation of a more elastic socket are relativevely small. The reduction of BMD in de cortical bone was lower compared to the reduction in BMD seen for cancellous bone. This could be attributed to the peripheral fit and fixation seen in cementless hemispherical press fit sockets. We found the same peripheral strain distributions in our FEA model described in chapter four.

A potential drawback, when interpretating the results found in chapter six, is that the BMD was measured with DEXA scans. Dexa scanning prevents differentiation between cortical and cancellous bone. In chapter seven we therefore used CT BMD measurements with which both the cortical and cancellous BMD can be evaluated. Cortical and cancellous bone exhibit variable stress reactions due to a difference in elasticity and contact stresses surrounding cementless sockets. Adding the BMD changes for both types of bone could blurr BMD changes of the specific bone types. Using the more specific CT BMD measurements to destinguise between cortical and cancellous bone, we were unable to confirm our hypotheses on elastic sockets preventing acetabular stress shielding. Based on the combined result from chapters four, six and seven we could not substantiate our primary hypothesis; a cup with a lower elastic modulus will result in a more physiological stress transfer across the acetabular bone and will diminish the effect of stress shielding and reduce the decline of acetabular BMD after the implantation of an acetabular component. Bases on the combined results from chapters four, six and seven, we could not substantiate the primary hypothesis of this thesis.

When contemplating the failure to support our hypothesis on the prevention of acetabular stress shielding using an elastic socket, we should acknowledge other factors that affect peri-prosthetic acetabular bone quality. Shape and characteristics of the implanted device may also have an effect on acetabular bone remodelling. Anatomical studies have showed the importance of the fascies lunata of the native hip [15]. Based on this concept, Rushton and Field developed a ‘horseshoe shaped’ socket with a more optimal bone deformation and bone remodelling capacity. [16-18] In a comparative study, results showed a superior (i.e. more physiological) stress distribution onto the acetabular bone by the horseshoe socket compared to standard hemispherical shaped sockets. [19] Complementary to the design, variable wall thickness of the socket could also create a more physiological stress distribution onto the surrounding acetabular bone. [20]

Furthermore the coating characteristics of sockets could also play a role in optimization of stress distribution. These characteristics affect friction, ingrowth potential and subsequent stress distribution onto the surrounding bone. [21,22]
When performing hip arthroplasty the surgeon tries to reconstruct the osteoarthritic hip and restore normal hip biomechanics. The centre of rotation, femoral offset and the biomechanics after hip arthroplasty change stress distribution onto the acetabular bone. [23] Besides the introduced hardware, muscles forces acting around the hip joint and providing movement also play a role in peri-prosthetic stress levels and subsequent bone remodeling of the acetabular bone around the implant. [24]

Wolfs Law

With the knowledge accumulated through literature research and data gathered through this thesis we appraised a legendary law in bone metabolism: when Julius Wolff encapsulated the principles on bone metabolism in the biomechanical law, know as Wolff's Law, the original concept was used to describe the re-organization of trabecular bone during growth and development. This concept has been promoted to describe the entire bone metabolism process. In subsequent decades after the publication of Wolff's law, it has become apparent that bone adaptation in vivo should be regarded as a complex system influenced by many biological and mechanical factors. Explanation of this multifactorial process using a "law" described in 1892 could be deemed insufficient and outdated because of the multiple influencing factors and biomechanical pathways that collectively have an effect on bone metabolism.

In conclusion this thesis found good clinical and radiological results of the cementless RM press fit elastic socket. However, the ultimate hypothesis of this thesis 'a cup with elastic properties close to bone will reduce stress shielding and the subsequent decline of acetabular BMD' could not be supported. On the contrary, this thesis suggests that stress and strain adaptation in acetabular bone cannot be resolved by changes in implant elasticity alone. Other factors such as socket geometry, hip biomechanics, socket position, fixation method, articulation and patient characteristics (age, gender, activity level, comorbidity) together could also determine the amount of bone adaptation and long-term survival.

Literature:

1. Hailer NP, Garellick G, Kärrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register. Acta Orthop. 2010;81:34-41.
2. Pedersen AB, Mehnert F, Havelin LI, Furnes O, Herberts P, Kärrholm J, Garellick G, Mäkela K, Eskelinen A, Overgaard S. Association between fixation technique and revision risk in total hip arthroplasty patients younger than 55 years of age. Results from the Nordic Arthroplasty Register Association. Osteoarthritis Cartilage. 2014;22:659-67.
3. Katz JN, Losina E, Barrett J, Phillips CB, Mahomed NN, Lew RA, Guadagnoli E, Harris WH, Poss R, Baron JA. Association between hospital and surgeon procedure volume and outcomes of total hip replacement in the United States medicare population. J Bone Joint Surg. 2001;83:1622-9.
4. Espehaug B, Furnes O, Engesaeter LB, Havelin LI. 18 years of results with cemented primary hip prostheses in the Norwegian Arthroplasty Register: concerns about some newer implants. Acta Orthop. 2009;80:402-12.
5. Engh CA, Hopper RH, Jr, Engh CA., Jr Long-term porous-coated cup survivorship using spikes, screws, and press-fitting for initial fixation. J Arthroplasty. 2004;19(suppl 2):54–60.
6. Hirashima Y, Ishiguro N, Kondo S, Iwata H. Osteoclast induction from bone marrow cells is due to pro-inflammatory mediators from macrophages exposed to polyethylene particles: a possible mechanism of osteolysis in failed THA. J Biomed Mater Res. 2001;56:177-83.
7. Crowninshield R, Maloney W, Wentz D, Humphrey S, Blanchard C. Biomechanics of large femoral heads: what they do and don't do. Clin Orthop Rel Res. 2004;429:102-7.
8. Wan Z, Boutary M, Dorr L. The influence of acetabular component position on wear in total hip arthroplasty. J Arthroplasty. 2008;23:51-6.
9. Udomikiat P, Dorr L, Wan Z. Cementless hemispheric porous-coated sockets implanted with press-fit technique without screws: average ten-year follow-up. J Bone Joint Surg. 2002;84:1195-200.
10. Vasu R, Carter DR, Harris WH. Stress distributions in the acetabular region--I. Before and after total joint replacement. J Biomech. 1982;15:155-64.
11. Periasamy K, Watson WS, Mohammed A, Murray H, Walker B, Patil S, Meek RM. A randomised study of peri-prosthetic bone density after cemented versus trabecular fixation of a polyethylene acetabular component. J Bone Joint Surg. 2011;93:1033-44.
12. Carter DR, Vasu R, Harris WH. Stress distributions in the acetabular region--II. Effects of cement thickness and metal backing of the total hip acetabular component. J Biomech. 1982;15:165-70.
13. Sano K, Ito K, Yamamoto K. Changes of bone mineral density after cementless total hip arthroplasty with two different stems. Int Orthop. 2008;32:167-72.
14. Kress AM, Schmidt R, Vogel T, Nowak TE, Forst R, Mueller LA. Quantitative computed tomography-assisted osteodensitometry of the pelvis after press-fit cup fixation: a prospective ten-year follow-up. J Bone Joint Surg. 2011;93:1152-7.
15. Daniel M, Iglic A, Kralj-Iglic V. The shape of acetabular cartilage optimizes hip contact stress distribution. J Anat. 2005;207:85-91.
16. Brooks R, Jones E, Storer A, Rushton N. Biological evaluation of carbon-fibre reinforced polybutyleneterephthalate (CFRPBT) employed in a novel cup. Biomaterials. 2004;25:3429–38.

17. Field RE, Cronin MD, Singh PJ, Burtenshaw C, Rushton N. Bone remodeling around the Cambridge cup: a DEXA study of 50 hips over 2 years Acta Orthop. 2006 77:726-32.
18. Ghosh R, Gupta S. Bone remodelling around cementless composite acetabular components: the effects of implant geometry and implant-bone interfacial conditions. J Mech Behav Biomed Mater. 2014;32:257-69.
19. Manley MT, Ong KL, Kurtz SM.The potential for bone loss in acetabular structures following THA. Clin Orthop Relat Res. 2006;453:246-53.
20. Hedia HS, Abdel-Shafi AA, Fouda N. Shape optimization of metal backing for cemented acetabular cup. Biomed Mater Eng. 2000;10:73-82.
21. Keaveny TM, Bartel DL. Effects of porous coating and collar support on early load transfer for a cementless hip prosthesis. J Biomech. 1993;26:1205-16.
22. Tanzer M, Kantor S, Rosenthall L, Bobyn JD. Femoral remodeling after porous-coated total hip arthroplasty with and without hydroxyapatite-tricalcium phosphate coating: a prospective randomized trial. J Arthroplasty. 2001;16:552-8.
23. Mulier M, Jaecques SV, Raaijmaakers M, Nijs J, Van der Perre G, Jonkers I. Early periprosthetic bone remodelling around cemented and uncemented custom-made femoral components and their uncemented acetabular cups. Arch Orthop Trauma Surg. 2011;131:941-8.
24. Fernandez J, Sartori M, Lloyd D, Munro J, Shim V. Bone remodelling in the natural acetabulum is influenced by muscle force-induced bone stress. Int J Numer Method Biomed Eng. 2014;30:28-41.

Hoofdstuk 10:

Samenvatting

Sinds de jaren zestig is het de heuppioniers en wetenschappers gelukt om reproduceerbare en goede lange termijn resultaten te verkrijgen bij het implanteren van heupprothesen. Vanwege de wens van patiënten om gedurende een groter deel van hun leven een hogere mate van kwaliteit van leven te behouden, zal de heupchirurg steeds meer gevraagd worden om over te gaan tot het implanteren van een totale heup arthroplastiek (THA) bij oudere maar ook bij steeds jongere patiënten.
Door de progressie in de kennis en kunde van de heupchirurg alsmede ook de enorme groei in de perioperatieve medische ondersteuning, is het mogelijk geworden een steeds breder leeftijdsgebied te helpen om de gewenste kwaliteit van leven te bereiken.
Doordat er steeds jongere patiënten geholpen kunnen worden zal ook de noodzaak tot het reviseren van de THA toenemen.
Het acetabulaire deel is en zal voor de aankomende tijd de belangrijkste reden zijn voor het reviseren van een THA.
Naast de tribologie en biomechanica van de THA, zal voor de heupchirurg de kwaliteit van het periarticulaire bot en de behandeling van deficiënties daarvan tijdens eventuele revisies de belangrijkste uitdaging blijven gedurende de aankomende decennia. Het onderliggende onderzoek heeft zich gericht op het bestuderen van de overleving, stabiliteit en periacetabulaire botremodelering rondom een elastische ongecementeerde cup en de reactie van het acetabulaire bot bij de implantatie van andere acetabulaire componenten.

In ***hoofdstuk 1*** beschrijven we in het kort de historische ontwikkeling van de THA. Op basis van de literatuur blijkt de belangrijkste reden voor een revisie van een THA het falen van de cup te zijn. De verschillende factoren die als oorzaak geduid kunnen worden voor een heup revisie operatie, worden in dit hoofdstuk beschreven. In 1892 beschreef Julius Wolff de wet van Wolff in het boek "Das Gesetz der Transformation der Knochen". Hierin beschreef hij de relatie tussen het bot en de daarop inwerkende krachten. De wet van Wolff gaat er vanuit dat het bot zich aanpast aan de krachten die de omgeving er op uitoefent. Wanneer de omgevingskrachten toenemen zal het bot zich remodeleren om meer krachten te kunnen weerstaan. Wanneer de omgevingskrachten verminderen, zal de botdichtheid afnemen, waardoor de botmatrix in de tijd zal verzwakken. Het verzwakken van het acetabulaire bot (stress shielding) na de implantatie van een cup werd eerder beschreven in de orthopedische literatuur en werd toegeschreven aan de rigiditeit van de cup.
Het ontlasten van het acetabulaire bot achter de cup, waardoor er een afname van kwaliteit en structurele eigenschappen ontstaat, was de aanleiding voor het ontwikkelen van onze ultieme hypothese: een cup met elastische kenmerken en een stijfheid die grenst aan die van bot zal tegen stress shielding beschermen en de afname van acetabulaire botdichtheid na een cup implantatie tegen gaan.

Sinds Sir Charnley in 1962 de basis legde voor de moderne heuparthroplastiek is de THA een zeer succesvolle orthopedische operatie gebleken. De basis voor dit succes was de gecementeerde THA. Gedurende de jaren zeventig groeide de interesse voor de ongecementeerde THA, doordat de revisies van gecementeerde protheses werden toegeschreven aan 'cement particle disease'. Deze visie bleek achteraf niet helemaal sluitend te zijn maar heeft wel geleid tot de verdere ontwikkeling van de ongecementeerde heupprothesiologie. De optimale fixatie methode voor de cup is echter tot op heden nog niet bepaald. In ***hoofdstuk 2*** hebben we een systematische literatuur studie uitgevoerd met behulp van Medline en Embase databanken. Door gebruik te maken van korte -en lange termijn klinische en radiologische parameters, hebben we geprobeerd bewijs aan te voeren voor de superioriteit van gecementeerde of ongecementeerde cups. Wij vonden enkele gerandomiseerde en niet gerandomiseerde studies waarin gecementeerde en ongecementeerde cups werden vergeleken. Een best evidence synthese analyse werd gedaan voor complicaties, slijtage, osteolyse, migratie en klinische uitkomsten. Deze analyse toonde bij de gerandomiseerde studies geen superioriteit voor de gecementeerde noch de ongecementeerde cup. Bij de niet gerandomiseerde studies werd echter voor de gecementeerde cup minder slijtage en een betere overall survival gezien. De ongecementeerde cup liet echter minder osteolyse, minder migratie en een betere aseptische overleving zien.

Als conclusie van hoofdstuk 2 kunnen we stellen dat er geen bewijs van superioriteit is wanneer we ongecementeerde en gecementeerde cups vergelijken. We adviseren orthopedisch chirurgen een bewezen gecementeerde of ongecementeerde cup te kiezen die past bij de patiënt en de aanwezige kennis en ervaring van de orthopeed.

In 2012 publiceerde de Nederlandse Orthopaedische Vereniging (NOV) een lijst met de beste gecementeerde en ongecementeerde heupprothesen. Na de benodigde updates en aanpassingen biedt de lijst, die gevonden kan worden op www.mijnheupprothese.nl, een handvat voor de heupchirurg om zijn of haar patiënten optimaal te kunnen behandelen.
In het Verenigd Koninkrijk werd door middel van het Orthopaedic Data Evaluation Panel (ODEP www.odep.org.uk) een nog uitgebreidere lijst van heupprothesen samengesteld.

Ter evaluatie van de kwaliteit van de verschillende onderdelen van een THA werden er door de National Institute of Healthcare and Clinical Excellence (NICE) verschillende richtlijnen en criteria beschreven. Deze NICE criteria stellen dat iedere willekeurige heupprothese aan een revisie ratio van 10% of minder voor elke prothese na 10 jaar of een vergelijkbare voorspellende overlevingsverwachting na 3 jaar moet voldoen.

De overleving van acetabulaire componenten is afhankelijk van verschillende korte en lange termijn factoren: slijtage, osteolyse en septische of aseptische loslating.
Osteolyse van het acetabulaire bot lijkt een belangrijke rol bij de overleving van een cementloze cup te spelen. Osteolyse is het gevolg van polyethyleen (PE) partikels en segmentale stress shielding van het acetabulaire bot achter cups. In ***hoofdstuk 3*** werd een ongecementeerde elastische monoblock cup gevolgd ter beoordeling van de aseptische overleving en acetabulaire osteolyse in een cohort van jonge patiënten. De totale overleving was 80 % na 10 jaar met een 98% overlevingsratio voor aseptische loslating. De gemiddelde PE slijtage bedroeg 0.11 mm/jr. Bij 3% van de patiënten werd een progressieve acetabulaire osteolyse gezien. Aan het einde van dit hoofdstuk observeerden wij een lage mate van acetabulaire osteolyse, een acceptabel PE slijtage niveau, een naar tevredenheid stellende overall overlevingsniveau en een excellente overleving voor aseptische loslating van een cementloze, elastische monoblock cup bij patiënten jonger dan 50 jaar. Verdere ontwikkelingen op het gebied van tribologie en kennis van bot adaptatie rondom cups zal de mate van slijtage en osteolyse verlagen en resulteren in nog betere overlevingsresultaten van cementloze cups.

Dit hoofdstuk toont aan dat er goede klinische en radiologische resultaten te verwachten zijn bij het gebruik van de ongecementeerde elastische monoblock cup in patiënten jonger dan 50 jaar.

Naast de tribologische ontwikkelingen, het gebruik van highly cross-linked PE of keramische op keramische lagering om slijtage tegen te gaan en osteolyse te verminderen, verwijzen sommige onderzoekers naar de wet van Wolff als veroorzaker van de achteruitgang van de acetabulaire bot kwaliteit na het plaatsen van een prothesecomponent. Met name bij ongecementeerde cups treedt er een verandering op in de geleiding van de articulaire krachten tussen het femorale en het acetabulaire bot na het plaatsen van een cup. Femorale stress shielding is een geaccepteerde oorzaak voor femorale osteolyse en revisie chirurgie. Acetabulaire stress shielding is een minder geaccepteerd faalmechanisme. Echter, er zijn aanwijzingen dat dit tot een verhoogde mate van acetabulaire osteolyse leidt met aseptische loslating van de cup als resultaat. Om deze hypothese te toetsen hebben we voor ***hoofdstuk 4*** een 3 dimensionaal eindig elementen model gebruikt om de effecten van flexibele cups op het fenomeen stress shielding te onderzoeken. Verschillende cups gemaakt van PE (casus1), PE met een metaal op metaal articulatie (casus 2)en een PE insert in een metalen behuizing (casus3) werden in het model gesimuleerd. We hebben de energiedichtheden in het bot en de microbewegingen tussen bot en de ongecementeerde cups vergeleken gedurende een loopcyclus. In ons eindig elementen model liet cup casus 1 de hoogste microbewegingen zien gedurende het lopen (400 μm). De meest rigide cup (casus 3) liet kleinere zones met hogere microbewegingen zien. Er van uitgaande dat er maximaal 50 microns bewogen mag worden om ingroei te faciliteren, zagen we bij de meest flexibele cup (casus 1) 40% ingroei oppervlakte. Casus 2 en 3 lieten een ingroei oppervlakte zien van meer dan 60% over de gehele bot-cup interface. Tijdens onze analyse vonden we dat de introductie van een cup een veranderd spanningsveld creëerde rondom de cup in vergelijking tot een normaal en intact heupgewricht. Dit werd niet veranderd door het inbrengen van een meer flexibele cup. 1,5 mm boven de geïmplanteerde cup zagen we geen veranderingen van botspanning, onafhankelijk van de flexibiliteit van de cup, in vergelijking tot het normale heupgewrichtmodel.

Aan het einde van dit hoofdstuk kunnen we concluderen dat de flexibiliteit van de cup in deze niet computer simulatie studie, geen invloed lijkt te hebben op de spanningspatronen rondom de ingebrachte cup.

Onze eindig elementen studie toonde aan dat meer flexibiliteit van de cup leidt tot hogere regionale microbeweging welk van invloed kan zijn op de ingroei van het acetabulaire bot, de initiële stabiliteit en overleving van de cup. Wanneer we meer elasticiteit (flexibiliteit) van de cup als een potentieel antwoord zien op acetabulaire stress shielding en osteolyse dienen we het effect van de flexibiliteit op de ingroei en initiële stabiliteit van de press-fit titanium gecoate monoblock cup te onderzoeken. Met dit in het achterhoofd zijn we voor ***hoofdstuk 5*** een studie gestart om de stabiliteit met of zonder additionele schroeffixatie bij een unieke ongecementeerde, elastische monoblock cup te testen. Gedurende een 2 jarige follow-up periode werd met behulp van radio stereometrische analyse (RSA) de stabiliteit van de cup in beide groepen bepaald. In de groep zonder de additionele schroef fixatie zagen we een statistische significante hogere proximale migratie van de cup. Deze proximale migratie was echter onder de klinisch relevante drempelwaarde voor migratie. Bij de analyse van onze data zagen we na 2 jaar follow-up geen klinisch relevante migratie in beide groepen.

Gebaseerde op onderzoeksdata in hoofdstuk 5 vonden we geen bewijs dat de additionele schroef fixatie een bijdrage leverde aan de initiële radiologische stabiliteit en klinische resultaten van de ongecementeerde press-fit elastische cup.

Er zijn verschillende type ongecementeerde cups beschikbaar voor de heupchirurg, elk met een eigen elasticiteitsmodulus en fixatie methodiek. Press-fit cups worden geïmplanteerd met een zekere stressmoment op het omringende acetabulaire bot wat de lokale botstofwisseling beïnvloedt. Bij een cup met een schroeffixatie mechanisme bestaat er een andere stressverdeling op het omringende acetabulaire bot. Om de veranderingen van de acetabulaire botdichtheid na een press-fit rigide heup resurfacing (kobalt-chroom) en een bewezen schroefcup design (titanium met een PE insert) te evalueren werd voor ***hoofdstuk 6*** een gerandomiseerde studie uitgevoerd. De botdichtheid werd prospectief vanaf de preoperatieve fase tot aan 24 maanden postoperatief in 5 verschillende periacetabulaire regionen met behulp van dual-energie X-ray absorptiometry (DEXA) bepaald. Na analyse van onze data concluderen wij dat in tegenstelling tot onze hypothese, het periacetabulaire bot beter bewaard was gebleven rondom de meer rigide kobalt chroom press-fit cup in vergelijking met de schroefcup met een lagere elasticiteit modulus (titanium met PE insert).

In conclusie: in hoofdstuk 6 konden we geen beschermend effect mbt stress shielding vinden in het acetabulaire bot rondom de prothese bij het vergelijken van een meer rigide press-fit cup en een minder rigide schroefcup gemeten met behulp van DEXA scans gedurende de follow-up.

Het gebruik van DEXA voor botdichtheidsmetingen geeft onderzoekers een 2D beeld van een 3D structuur zonder onderscheid te kunnen maken tussen corticaal en spongieus bot. Wanneer er gebruik wordt gemaakt van kwantitatieve CT metingen, dan levert dit een 3D beeld op met een duidelijk onderscheid tussen corticaal en spongieus bot. Deze laatste methode kan echter alleen in onderzoeksverband worden toegepast vanwege de mate van straling die vrijkomt bij de CT botdichtheidmetingen gedurende de follow-up.

In ***hoofdstuk 7*** beoordelen we de spongieuze en corticale botdichtheidsveranderingen na de implantatie van een meer elastische cup. Middels kwantitatieve CT botmetingen werd tijdens een twee jaar durende single-centre prospectieve studie de acetabulaire botdichtheid bepaald.
Gedurende de studieperiode vonden we een significante afname van de spongieuze botdichtheid en een minimale daling van de corticale botdichtheid rondom het craniale deel van de elastische press-fit cup. De gevonden afname van botdichtheid trad met name op gedurende de eerste 6 maanden na implantatie. 6 -24 maanden na implantatie van de cup observeerden we een minimale reductie in spongieuze botdichtheid en een minimale stijging van de corticale botdichtheid.

Als conclusie van hoofdstuk 7 zagen we op basis van de resultaten van deze studie geen bewijs voor het voorkomen van acetabulaire stress shielding door een elastische cup.

Chapter 11:

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Chapter 12:

Curriculum Vitae

The author of this thesis was born on 23 October 1975 in the centre of the Netherlands, Apeldoorn. After spending his childhood on the soccer pitch he decided to become an orthopedic surgeon.

Faith decided that he would meet his future wife at the Koninkijke Scholen Gemeenschap de Maten in Apeldoorn in 1990. After his graduation from the HAVO, he enrolled into the Hogeschool Midden Nederland Utrecht (1993) were he was trained as a physiotherapist until 1996. Because his goal still was to become an orthopedic surgeon, he attended evening school at the Apeldoorn College VWO in Apeldoorn.

After his graduation and supported with his Physical Therapy training, he enrolled into Medical School at the University Utrecht in 1996.

During his internships he performed scientific research at the orthopedic department of the Radboud University and the St. Maartens Kliniek Nijmegen. During this period his interest for this thesis was awakened.

He started his clinical career working as a resident orthopedic surgery in the Elkerliek hospital in Helmond (Dr. J. Vegter). He performed his general surgery residency at the Deventer Hospital (Dr. M. Eeftinck Schattenkerk) after which he started his training as an Orthopaedic surgery resident at the Radboud University in Nijmegen (Prof. Dr. R. Veth), the St. Maartens Kliniek (Dr. A. Wymenga) and Rijnstate Hospital (Dr. W. Rijnberg) in 2007.

After finishing his training he worked at the Medisch Spectrum Twente Enschede during 2011 from where his ambitions to become a spinal / hip arthroplasty surgeon led him to switch to the Orthopedic Centre OCON (Almelo/Hengelo) in 2012. He is now a hip reconstruction and spine surgeon at the Orthopaedic Centre OCON.

Currently he is living in Almelo with his wife Ilona, whom he “finally” married in 2013, and his children Ryan and Myrthe.